AESCULAP®

SERVICE MANUAL

SUPPLIED BY: AESCULAP, INC.
1000 Gateway Boulevard
South San Francisco, CA 94080

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EQUIPMENT: CRANIOTOME POWER SYSTEM
Primary Components:
AESCULAP ELAN®-E Electrical Motor System with mobile stand, flexible cable, specified hand-pieces, and accessories
Stored in special packing container

Reference Date for SERVICE MANUAL: March 1994

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SYSTEM COMPONENTS:

May Be Found in the Sections of the Manual Referenced Below*

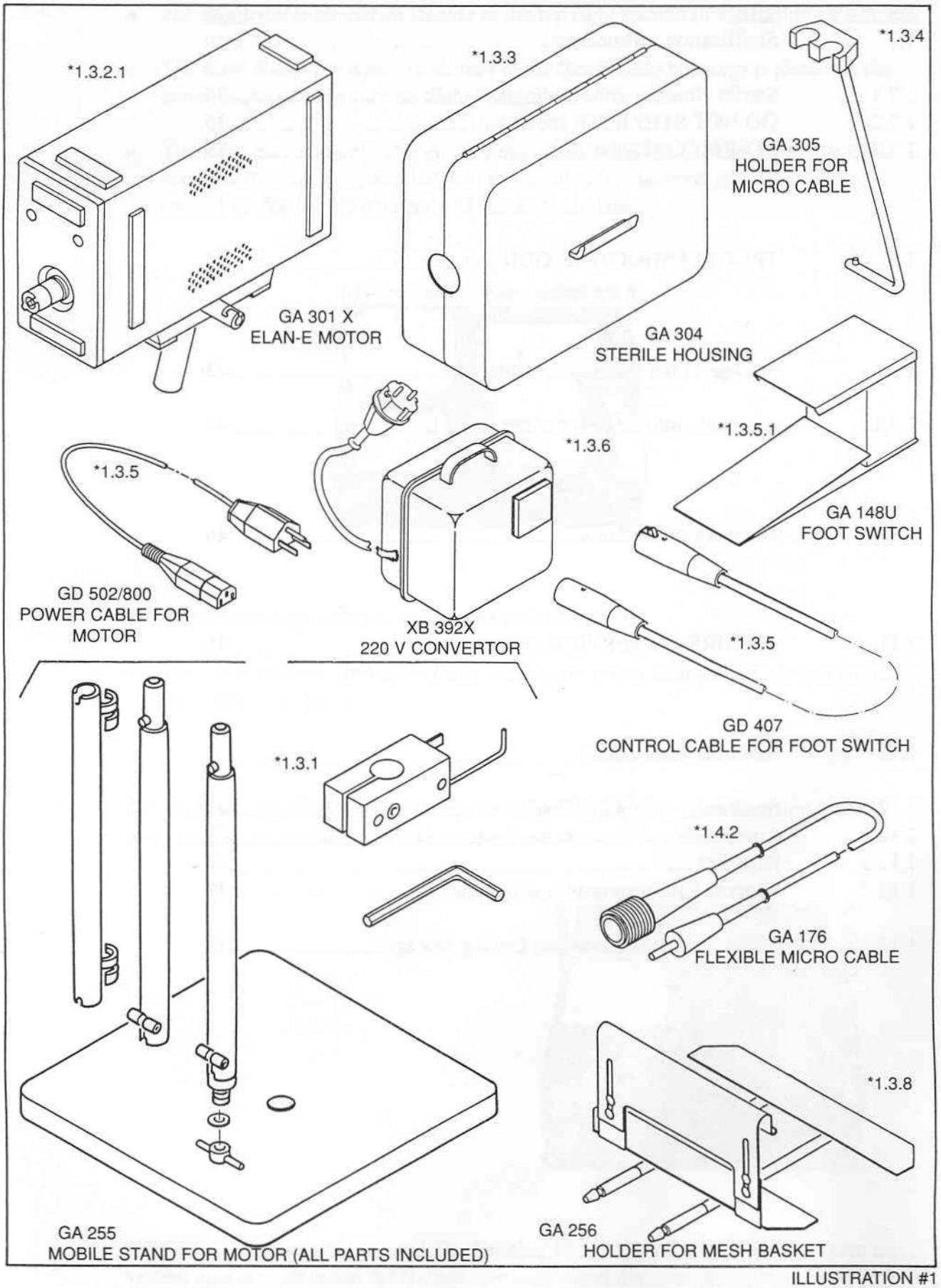


ILLUSTRATION #1

SYSTEM COMPONENTS:

May Be Found in the Sections of the Manual Referenced Below*

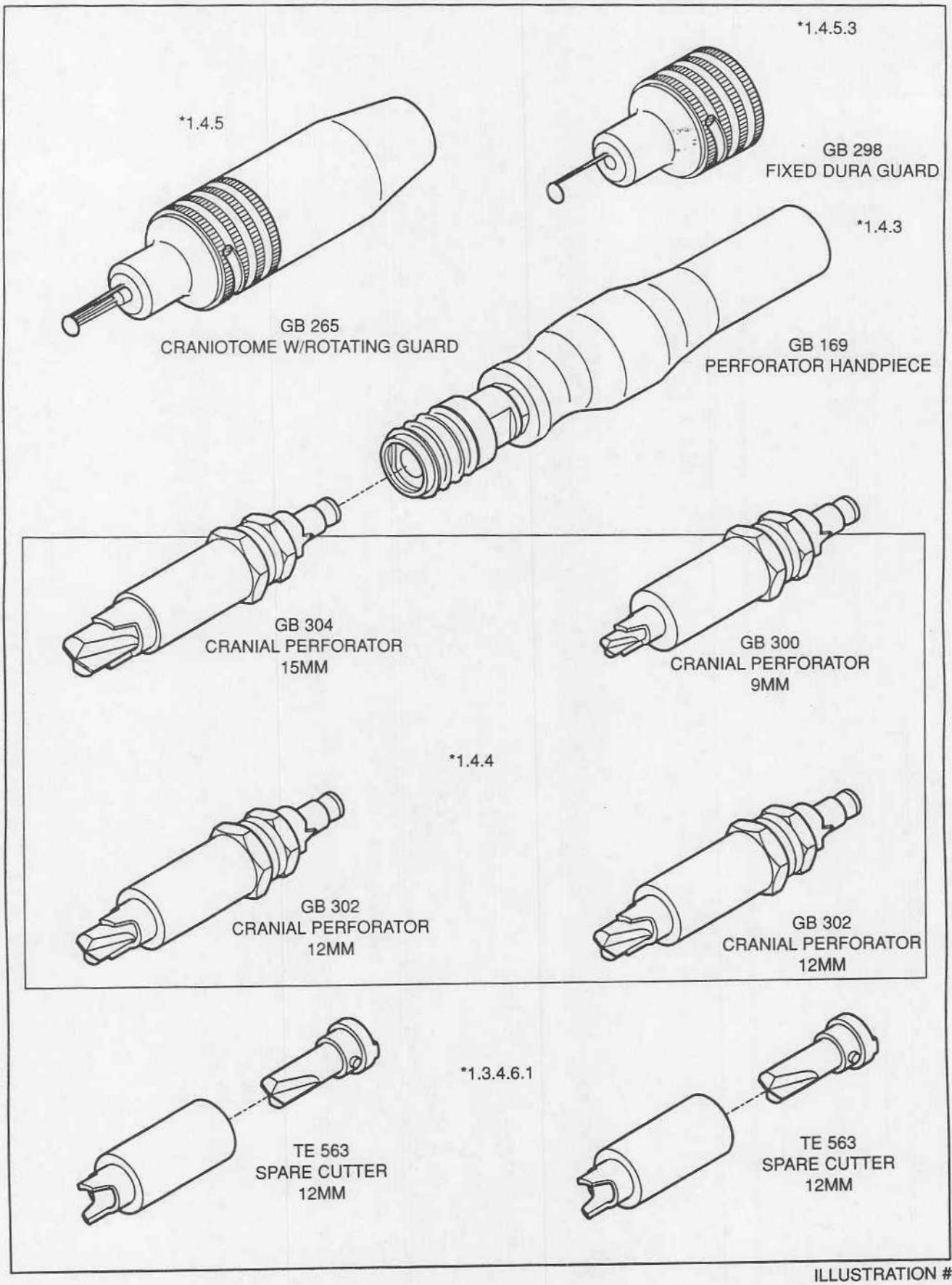


ILLUSTRATION #2

Parts Diagram for Elan-E Motor—Note: Diagram Provided for Reference Only

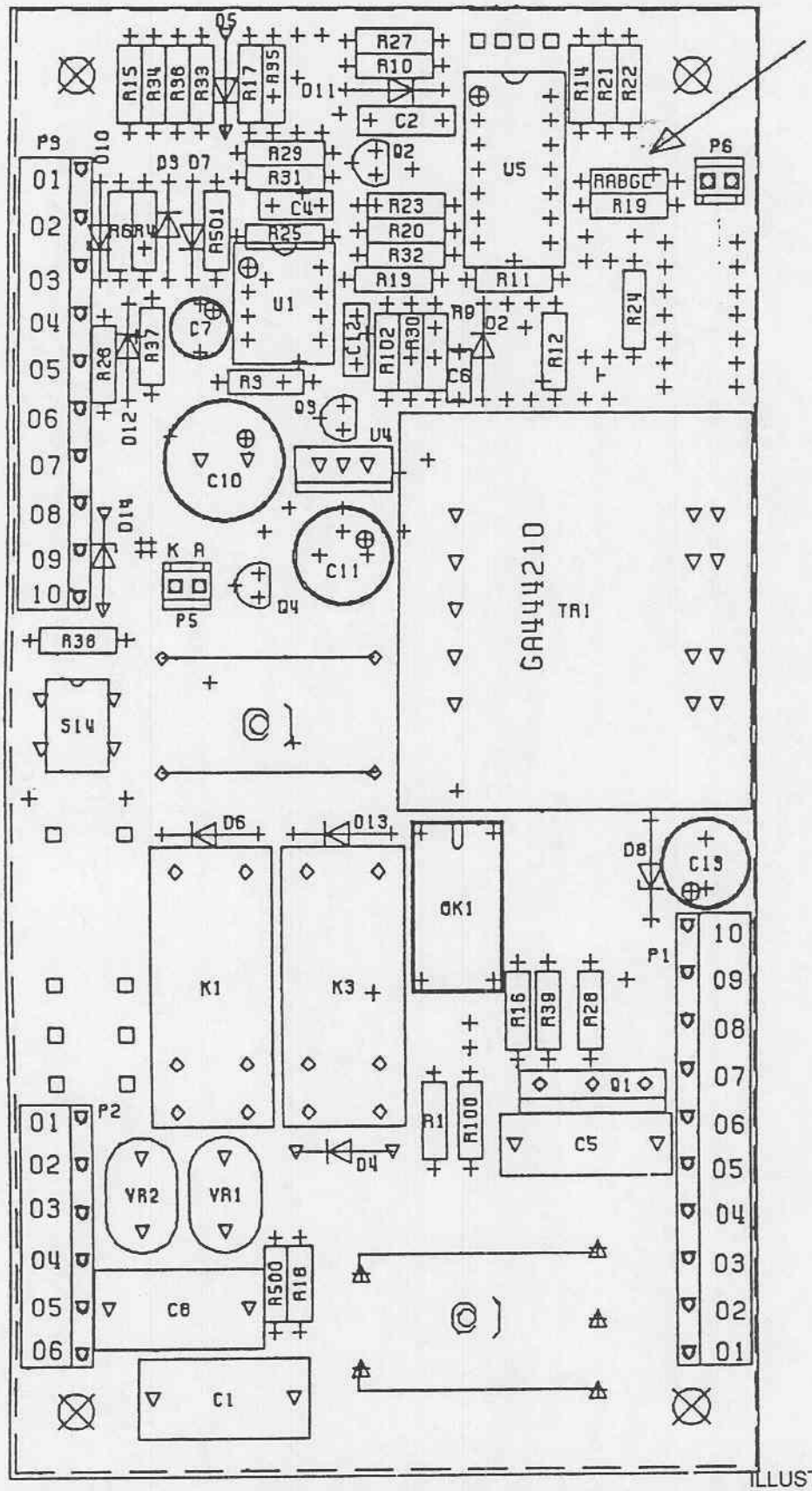


ILLUSTRATION #3

Motor is Sealed Unit—For Detailed Repairs, Return to the Manufacturer.

Wiring Diagram for Elan-E Motor—Note: Diagram Provided for Reference Only

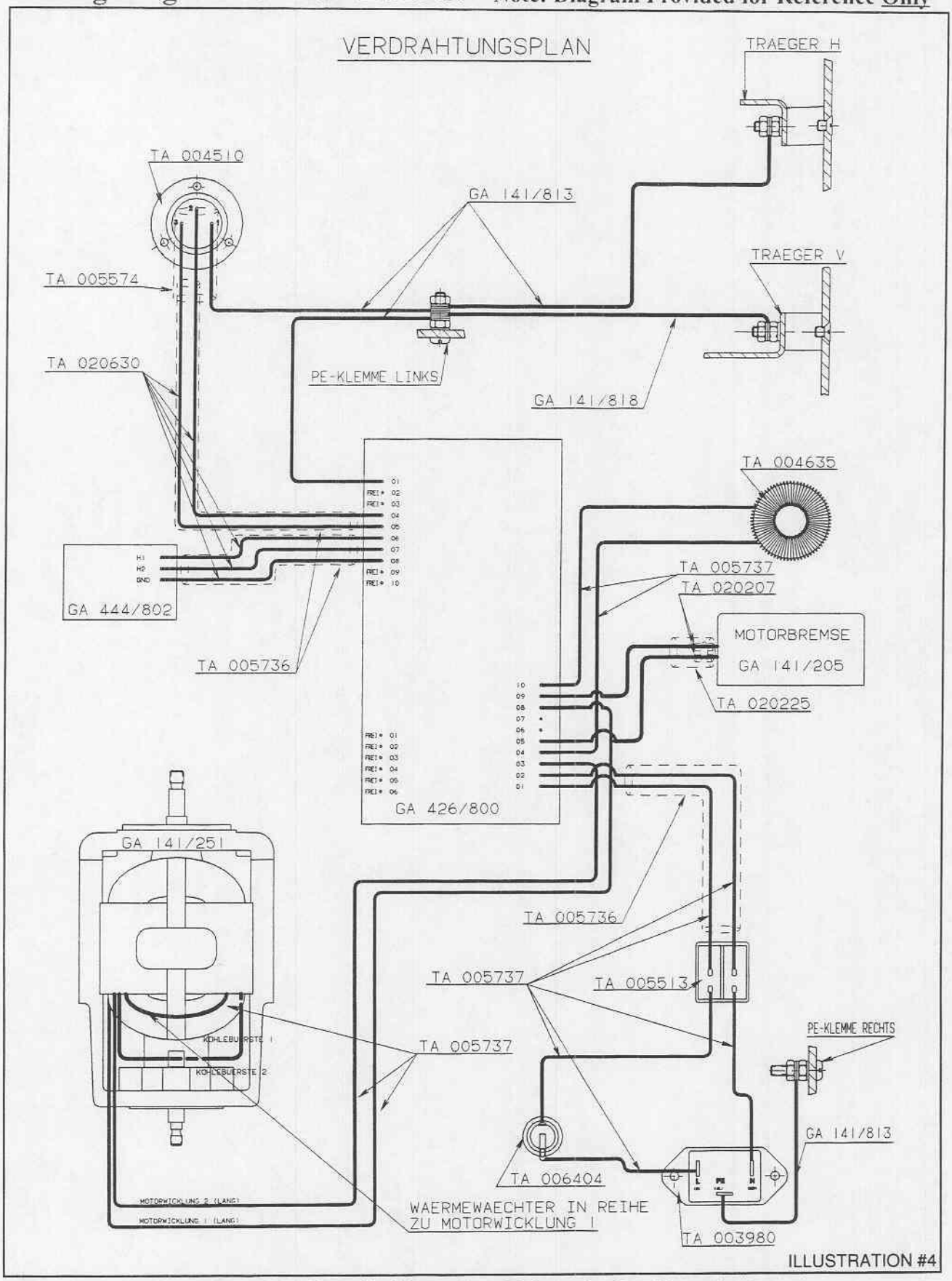


ILLUSTRATION #4

Motor is Sealed Unit—For Detailed Repairs, Return to the Manufacturer.

Parts Diagram for Footpedal—Note: Diagram Provided for Reference Only

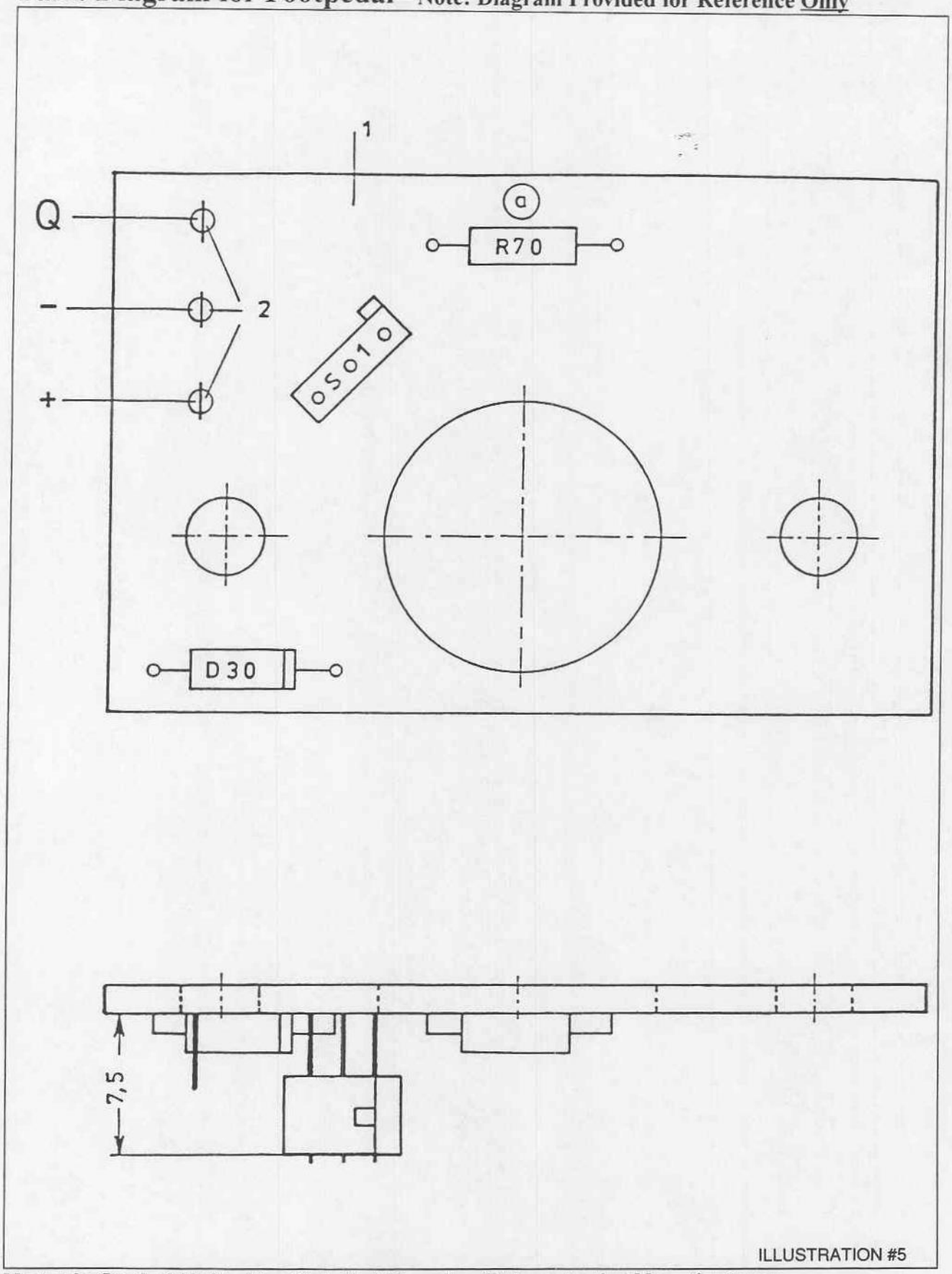


ILLUSTRATION #5

Motor is Sealed Unit—For Detailed Repairs, Return to the Manufacturer.

CRANIOTOME POWER SYSTEM

1.1 GENERAL DESCRIPTION:

The system is protected during storage and transport by a specially designed SAN Container with internal dividers (which organize and further protect the system components). The assembly of the components is described in the following section.

The Elan-E electric motor is mounted at the top of a mobile stand, and is enclosed by a Sterilizable Housing. Electrical cables are connected at the back of the motor, and are directed down the pole to the base of the mobile stand. The flexible micro cable connects to the front of the motor. Handpieces are organized in a mesh basket which is mounted onto a bracket on the mobile stand. Handpieces are easily removed from the basket and connected to the end of the flexible micro cable. The surgeon uses the footpedal to start the motor and control its speed. Handpieces are easily changed by depressing the release button on the distal end of the flexible micro cable.

After the bone flap has been turned, the distal end of the flexible cable is secured into a special holding device, and the mobile stand enables the surgical team to easily move the system away from the surgical field. At the end of the procedure, the system can then be rolled back to the field - for use of the wire pass drill (to secure the bone flap back in the patient).

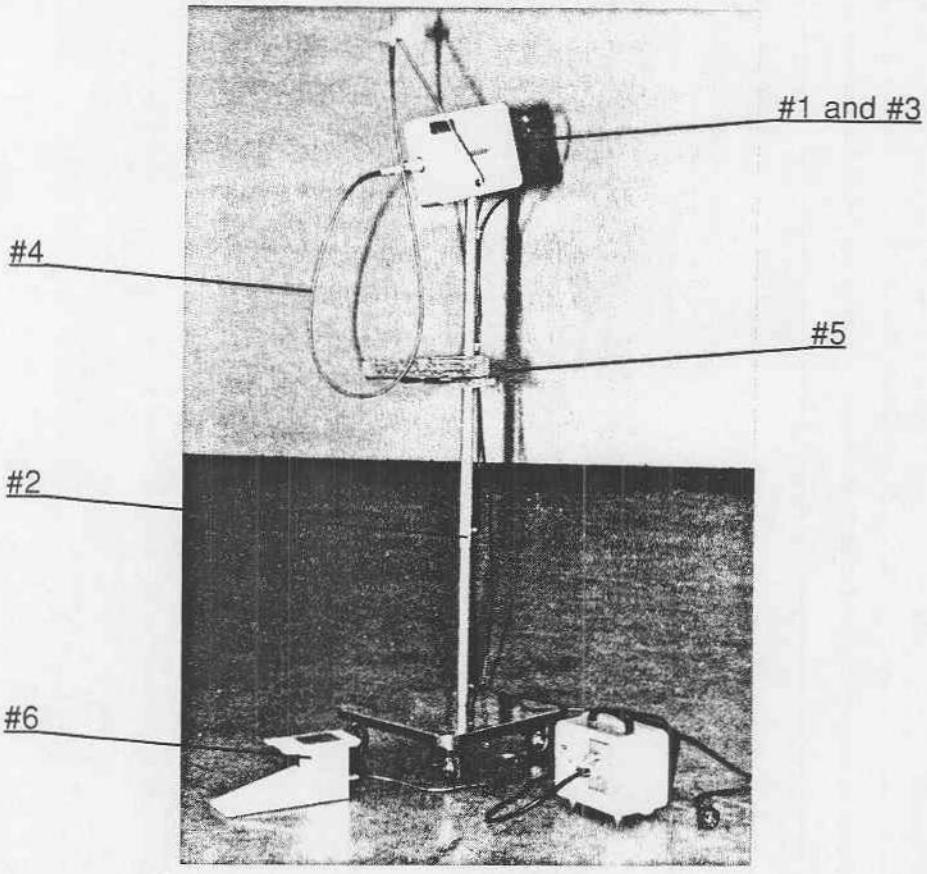
INSTRUCTIONS FOR USE (including points of CARE and HANDLING) must be followed to assure proper function of the handpieces and the system components.

1.1.1 ASSEMBLED SYSTEM:

The CRANIOTOME POWER SYSTEM is shown assembled and ready for use.

The primary components are:

1) The Elan-E electrical motor
2) Mobile stand
3) Sterilizable housing for the Elan-E motor
4) Flexible micro cable
5) Mesh basket - mounted by special bracket to the mobile stand
6) Footpedal for the electrical motor



1.2 TECHNICAL DATA:

1.2.1 Craniotome System in storage container

Length:	835MM (32 1/2")
Width:	615MM (24")
Depth:	270MM (10 1/2")
Weight:	
With system enclosed:	75.74 Kg (167 lbs)
Container only:	11 Kg (24.3 lbs)

1.2.2 Electrical transformer - VDE Approved

Voltage:	Converts 220V to 110V
Output frequency:	50 Hz

1.2.3 Electrical motor - UL Approved

Voltage:	110V
Rated current:	2 A
Frequency:	50/60 Hz
Maximum RPM:	18,000

Flexible cable (GA176) is electrically isolated from the motor.
NOTE: Do not sterilize the electrical motor.

1.2.4 Sterilizable housing for the electrical motor

Housing Material:	Anodized Aluminum
Sterilization:	
High Vac Autoclave:	Standard Cycle (270°)
Gravity Steam Autoclave:	Standard Cycle (250°)

1.2.5 Foot switch for the electrical motor

Does not carry 110V current flow.
Functions only as an electrical switch and speed regulator for the electrical motor.

1.2.6 Flexible micro cable (GA176)

Length:	180 CM

Flexible cable is electrically isolated from the motor.
Distal connection (to the handpieces) according to DIN Standard 13940.
Sterilization:

High Vac Autoclave:	Standard Cycle (270°)
Gravity Steam Autoclave:	Standard Cycle (250°)

1.2.7 Perforator handpiece (GB169)

Weight:	280 grams
Speed ratio:	20:1

Handpiece provided with HUDSON chuck adaptor.
Proximal connection (to the flexible micro cable) according to DIN Standard 13940.

1.2.8 Perforators

GB300 (small):	
Secondary (outer) cutter:	Ø 9MM
Primary (inner) cutter:	Ø 6MM
GB302 (medium):	
Secondary (outer) cutter:	Ø 12MM
Primary (inner) cutter:	Ø 9MM
GB304 (large):	
Secondary (outer) cutter:	Ø 15MM
Primary (inner) cutter:	Ø 12MM

Spare cutter (TE563): For medium size perforator (GB302)

Secondary (outer) cutter:	Ø 12MM
Primary (inner) cutter:	Ø 9MM

1.2.9 Craniotome (GB265):

Speed ratio: 1:1
Proximal connection (to the flexible micro cable) according to DIN Standard 13940.
Provided with Rotating Dura Guard (GB298) attached to the bottom section (GB267).
Rigid Dura Guard (GB266) is also provided.
No key is required to exchange the Dura Guard or replace the cutter.
Inner chuck accepts:
Cranio blades (MD879 - packaged sterile, 5/pkg per box)
Wire pass drill (US419 - packaged sterile, 5/pkg per box)

1.2.10 Half size container (JN010P)

Length:	286MM (11 1/4")
Width:	280MM (11")
Depth:	100MM (4")
Material:	Anodize aluminum, 2MM thick
Lid:	Perforated, with retention plate (TE673)
Bottom:	Perforated, with retention plate (TE673)
Filter material:	Disposable (US994)

1.2.11 Half size basket (JF489)

Length:	245MM (9 3/4")
Width:	254MM (10")
Depth:	30MM (2")
Material:	Stainless steel, wire mesh

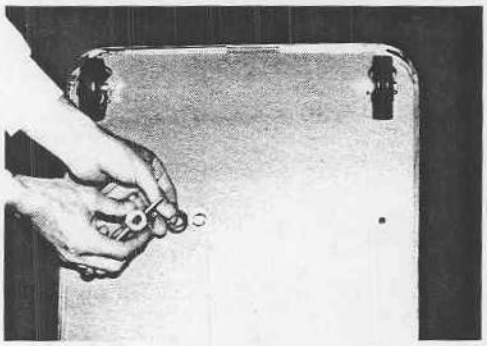
1.2.12 Storage box for supplies

Length:	24"
Width:	16"
Depth:	11"
Material:	High-density polyethylene plastic

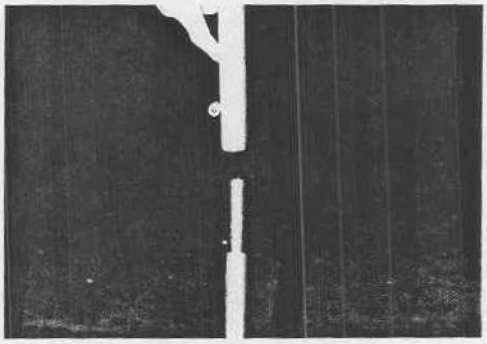
1.3 ASSEMBLY OF SYSTEM AND COMPONENTS:

1.3.1 Assembly of mobile stand:

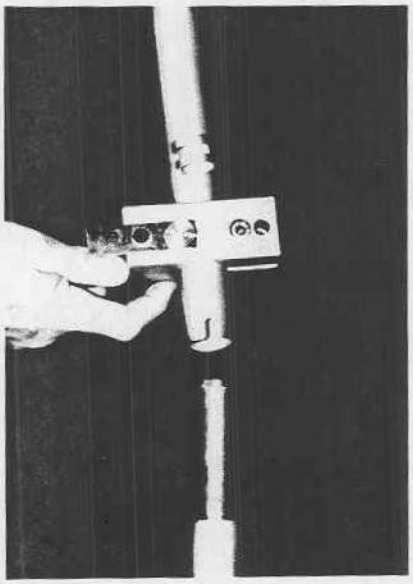
1.3.1.1 The **lower tube section** is pushed through the base of the mobile stand and secured in place with **special nut**.



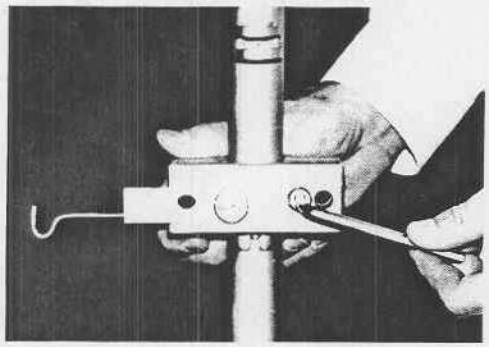
1.3.1.2 The **center tube section** is pushed onto the lower tube section.



1.3.1.3 The **fixation block** is pushed onto the base of the **upper tube section**.



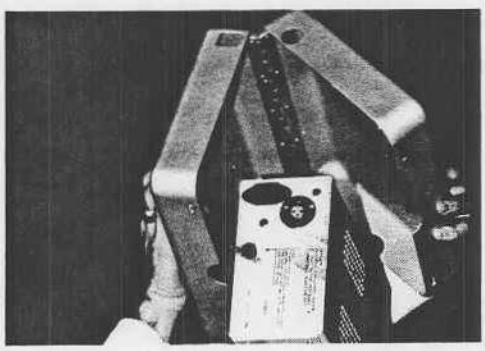
1.3.1.4 The fixation block and upper tube section are fitted in the **center tube section**. The **fixation block** is oriented with the base of the mobile stand, and the fixation block and upper tube section are secured with the **hex screw**.



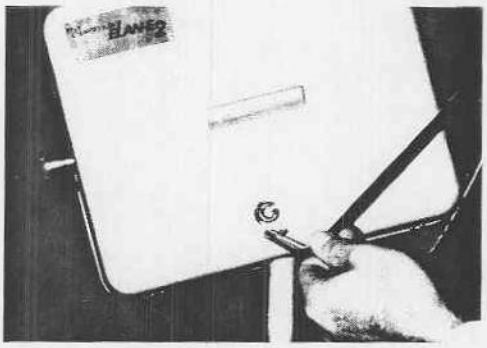
1.3.2 Mounting Elan-E motor onto the mobile stand:

1.3.2.1 Insert the **mounting post** of the motor into the upper tube section

1.3.3 On the back of the Elan-E motor, flip the motor switch to "ON", and then the motor is enclosed with the hinged **Sterilizable shield**.



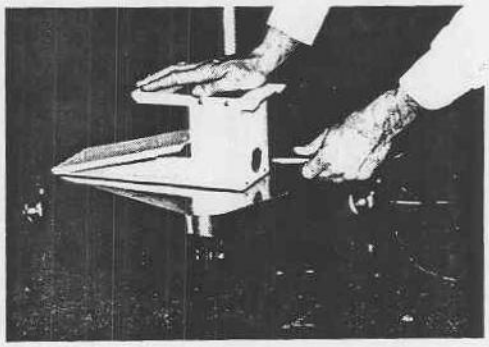
1.3.4 Insert the **Holding Device for the micro cable** into the slot in the side of the sterilizable shield. Then rotate the Holding Device forward (until it locks in place)



1.3.5 The **electrical power cable** and the **footpedal's control cable** are plugged into the back of the motor and the cables are directed through the guides on the back of the pole.

1.3.5.1 The control cable is plugged into the **footpedal**, and the footpedal can be set on the base of the mobile stand.

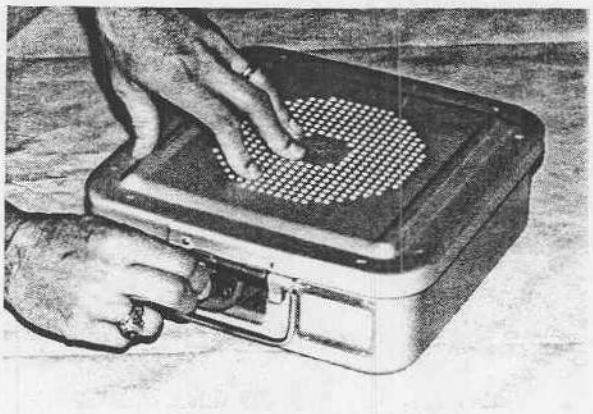
(The footpedal can remain on the base of the stand until the motor is placed at the desired location near the surgical field - and the footpedal can then be placed next to the foot of the surgeon performing the procedure).



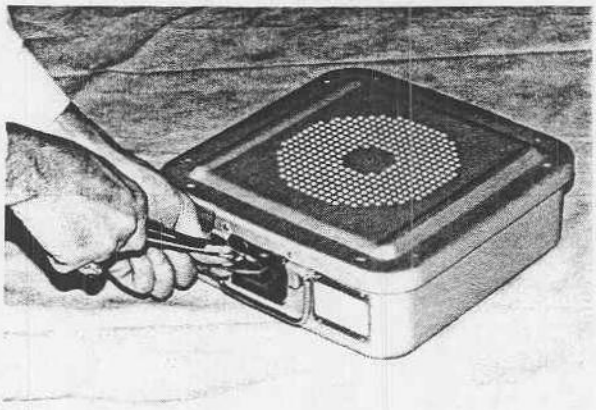
1.3.6 The **electrical transformer** is utilized when power supply to the Operating Room is **220 Volt**.

NOTE: The electrical motor runs only on 110 Voltage.

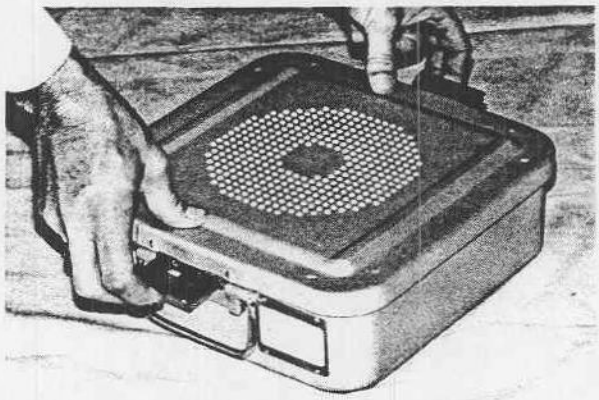
1.3.7 Open the STERILCONTAINER™ lid by "snapping-off" the **Tamperproof locks**.



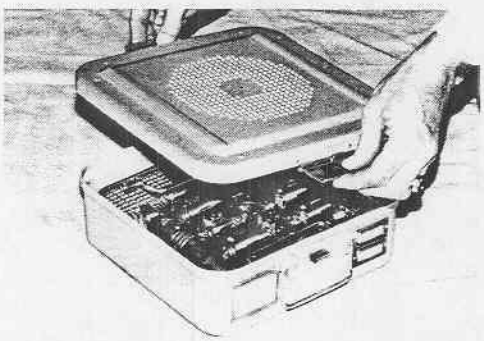
(OPTION: The lock can easily be cut with scissors, and then removed)



1.3.7.1 After the Tamperproof locks have been removed, *both* of the **lid tabs** can be opened.



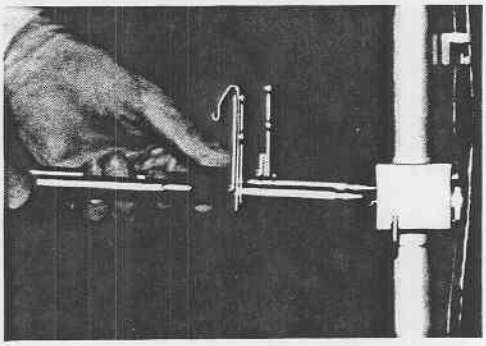
1.3.7.2 Remove the lid of the container by lifting with the lid tabs



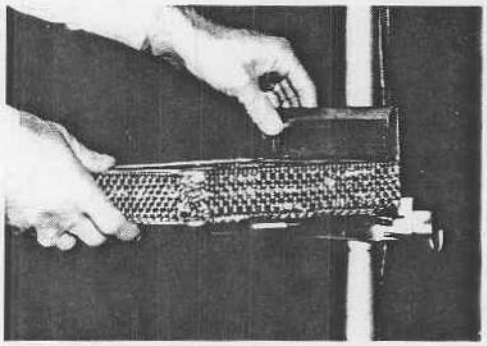
1.3.7.3 The **sterile mesh basket** is removed from the container

NOTE: The sterile basket can then be placed upon the sterile O.R. back table.

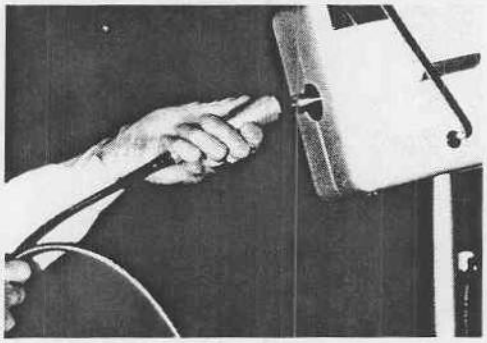
1.3.8 The **mounting bracket** is pushed into the fixation block until it *latches*.



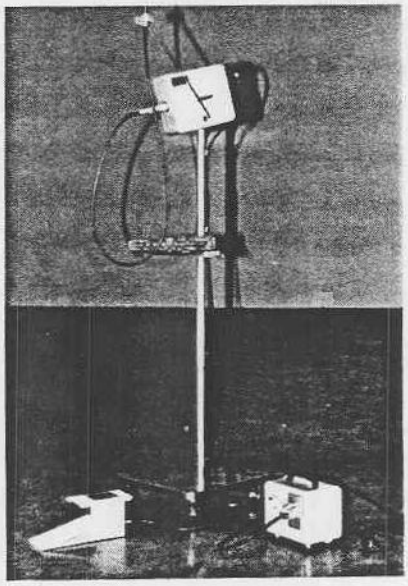
1.3.8.1 Secure the mesh basket onto its holding bracket on the mobile stand



1.3.9 Push the **flexible micro cable** onto the drive shaft of the motor until it engages with a "click", and the other end of the micro cable is secured in the holding device



1.3.10 **The ASSEMBLED Craniotome System.**



IMPORTANT:

To assure proper function of the system and its components, FOLLOW THE GUIDELINES PROVIDED in the INSTRUCTIONS FOR USE section of this manual.

1.4 INSTRUCTIONS FOR USE:

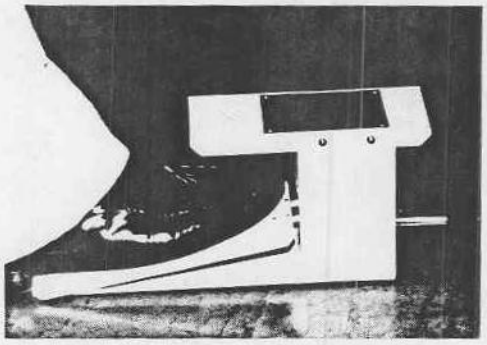
NOTE: AFTER THE SYSTEM HAS BEEN IN STORAGE and before the system is used in surgery:

- **The following handpieces must be sent to the hospital's Biomedical Engineering for special (sprayed-in) lubrication (GB149):**

  GB169 PERFORATOR HANDPIECE
  GB265 CRANIOTOME

1.4.1 **Elan-E Electric Motor**:
When the unit has been assembled (per above instructions), it is ready for use.

1.4.1.1 **Start the motor** by depressing the footpedal:



When the footpedal is depressed, the "click" heard inside the motor is the electromagnetic brake on the motor's drive shaft being released. The motor will then run freely.

1.4.1.2 **Establish the desired RPM of the motor** by progressively pushing down on the footpedal.

1.4.1.3 **Stop the motor** by lifting from the footpedal.
When the footpedal is released, the "click" inside the motor will again be heard (as the brake stops the rotation of the motor's drive shaft).

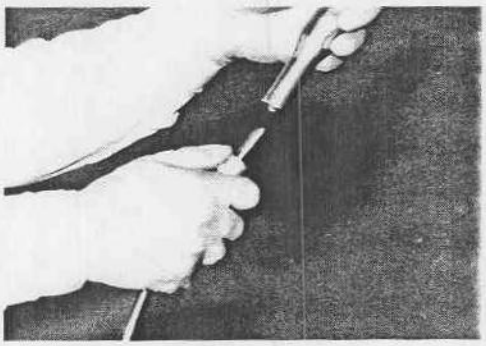
1.4.2 **Flexible micro cable (GA176)**:
Provides connection between the motor and the handpieces.

1.4.2.1 **To connect the micro cable** *to the motor*:

- First, cover the motor with the Sterilizable Housing, connect the cables to the motor, and insert the Cable Holder through the side of the Sterilizable Housing (see Assembly - 1.3.4).

- Then, grasp the large connector on the end of the cable, and push the connector onto the motor's driveshaft until it "clicks" in place (see Assembly - 1.3.9).

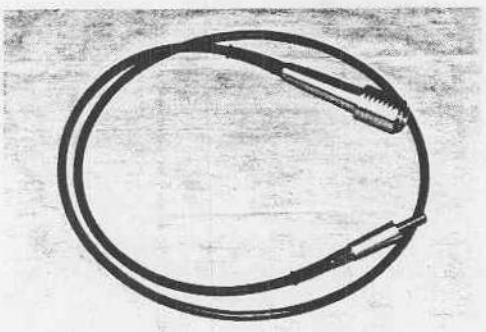
1.4.2.2 **To connect the micro cable** *to handpieces*:

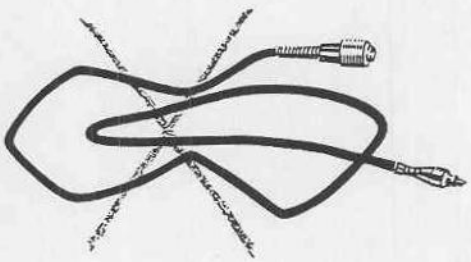


- Grasp the small connector on the end of the cable, and push the handpiece onto the connector until it "clicks" in place. The handpiece should then be checked for proper function, and either:

  - Passed to the surgeon, or
  - The end of the cable (with the handpiece) can be secured in the Cable Holder.

1.4.2.3 During use: **AVOID *KINKING* (causing a <u>tight bend</u> to form in) THE MICRO CABLE.**





KINKING the micro cable may cause abnormal friction (wear) of the cable and internal sheath. Excessive kinking of the cable may cause:

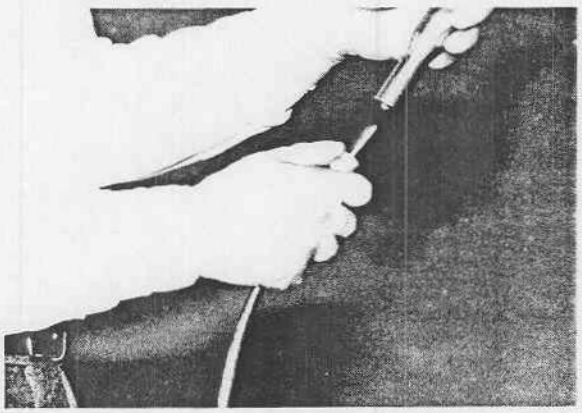
- The cable to become bent (excessive noise and vibration will then be felt in the cable during use of the system), or
- The braided wires of the cable will become frayed (excessive noise and vibration will then be felt in the cable during use of the system).

*If the cable becomes bent or frayed, it will need to be **replaced**.* Send the cable:

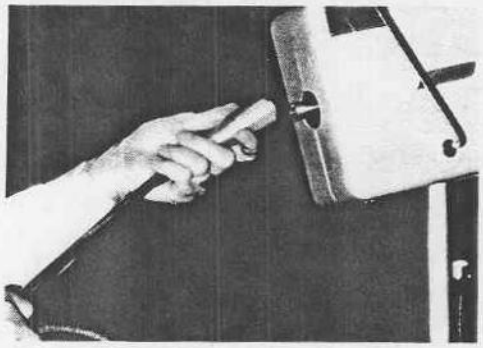
- To Biomedical Engineering (for evaluation - to confirm cable replacement is needed), or
- To AESCULAP's repair service (see Section 1.11.3 of this manual).

1.4.2.4 **To dis-connect the micro cable** *from handpieces*:

Grasp the cable, push the button on the connector, and remove the handpiece.

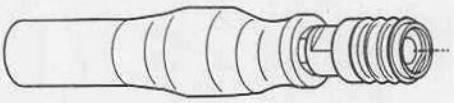


1.4.2.5 **To dis-connect the micro cable** *from the motor*:



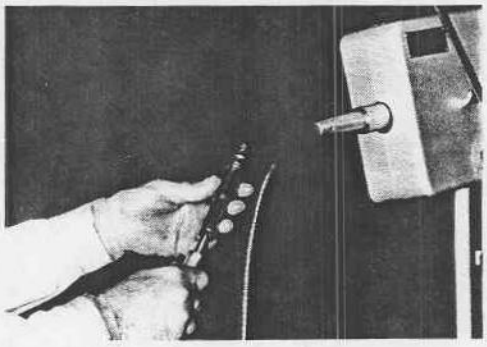
- Grasp the cable at the Large Connector,
- Slide the connector (towards the center of the cable) to release the "catch", and
- Pull the cable away from the motor (it should slide off easily).

1.4.3 **Perforator handpiece (with Hudson adapter)**:



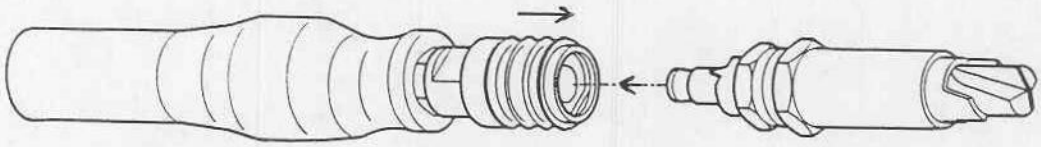
This handpiece connects to the micro cable, and reduces the speed in the ratio of 20:1 (e.g. with motor speed of 18,000 RPM, the speed at the tip of the handpiece is 900 RPM).

1.4.3.1 **To connect the handpiece** *to the micro cable*:



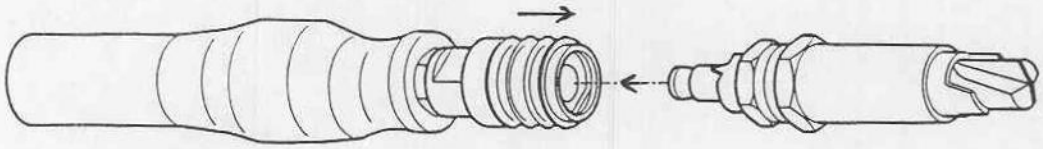
- Grasp the cable at the Small Connector,
- Push the handpiece onto the connector until a "click" is felt/heard.

1.4.3.2 **To connect the Perforator** *to the handpiece*:



- Grasp the handpiece,
- Pull back on the Hudson Connector,
- Line up the Hudson Connector with the Hudson fitting on the Perforator,
- Slide the Hudson fitting into the connector until it "snaps" securely in place.

1.4.3.3 **To dis-connect the Perforator** *from the handpiece*:



- Grasp the handpiece,
- Pull back on the Hudson Connector,
- The "catch" is released, and the Perforator can be easily pulled off.

1.4.4 Cranial Perforators:

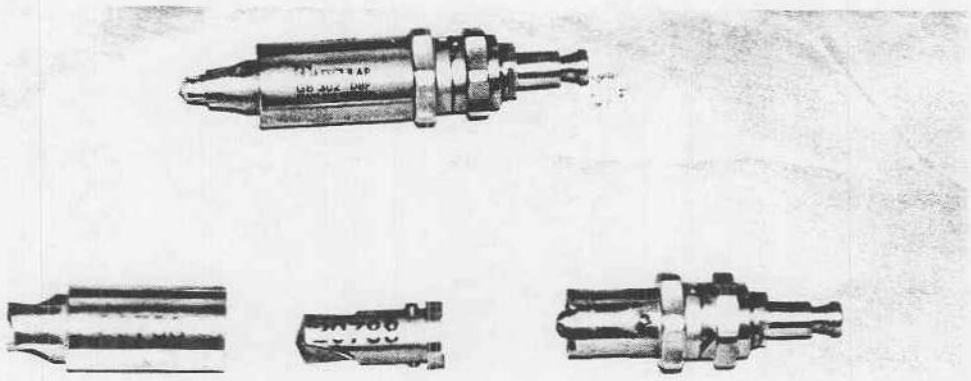
Caution: This device should only be used by a physician with appropriate training involving skull perforations.

Warning: *To avoid patient injury*, the perforator should not be used unless the surgeon is thoroughly familiar with the instructions and warnings contained within this manual.

Warning: **Proper care of this device is critical**. Follow instructions exactly as prescribed herein. The perforator may be resharpened or serviced *only by AESCULAP*. AESCULAP assumes no liability for any consequences if the device has been altered in any way, resharpened or serviced by a third party, or if the main body has been disassembled.

Caution: Federal Law (USA and Canada) restricts this device to sale by or on the order of a physician.

1.4.4.1 Basic design rationale

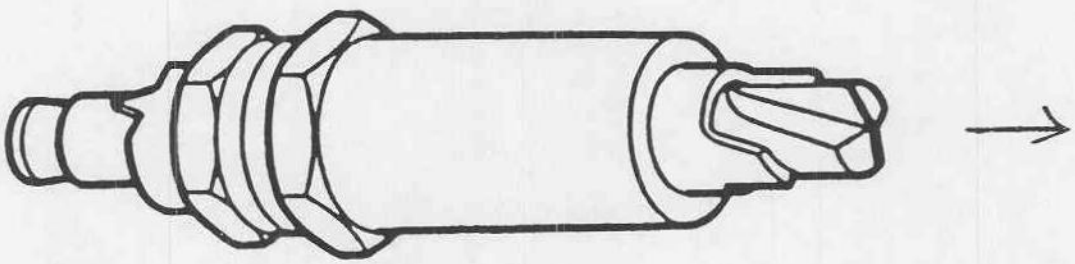


(1) The **primary** (inner) **cutter**
(2) The **sleeve** with the **secondary** (outer) **cutter**
(3) The **main body** with its spring loaded clutch mechanism

1.4.4.2 The Cranial Perforators function on the following principles:

a. **The two cutter bits are coupled, and will turn, *only* if the primary (inner) cutter is under sufficient axial pressure to overcome the internal spring mechanism (enabling the toothing of the internal "clutch" to *engage*).**

b. **When the primary cutter (which precedes the secondary cutter) has penetrated the inner table of the skull, the primary cutter is then *pushed forward slightly* by the spring in the internal "clutch". The toothing of clutch then disengages, and the secondary (outer) cutter stops the rotation of the perforator.**



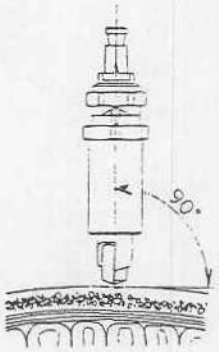
1.4.4.3 DIRECTIONS FOR USE:

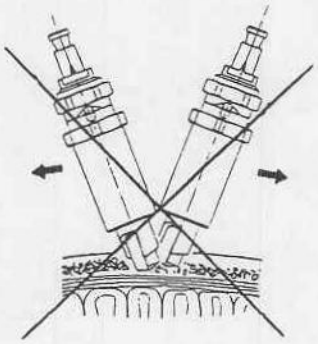
VERY IMPORTANT NOTICE: The Cranial Perforator is a fast-acting, powerful instrument for the precise, controlled, and rapid penetration of the skull. *To be effective,* ***a sharp drilling head is necessary*** *(to efficiently cut the bone with minimal heat development)*. Surgeons using the cranial perforator must be aware that these same attributes inevitably are endangering the delicate soft tissues immediately underneath the skull. While drilling must always be carried out with the utmost caution, some erosion of the dura surface by the primary cutter cannot always be avoided. This is especially the case in older patients whose dura is more fragile and usually adherent to the skull.

1. Test the integrity of the spring release mechanism of the internal "clutch" **before** attaching the perforator to the power source (see *Pre-drill test instructions*).

2. Place the tip of the perforator, **when it is not rotating,** firmly against the skull. Hold the skull. Grasp the perforator with the other hand, *and turn the* ***secondary cutter*** *back and forth slightly*. Watch the axial movement of the primary cutter, and apply sufficient pressure to secure clutch engagement.

3. **It is <u>essential</u> to keep the perforator perpendicular (at a 90° angle) to the patient's skull.**





4. **Start drilling slowly**, and gradually accelerate to full speed after the hole has been started.

   CAUTION: The split point of the primary cutter has been designed to prevent "walking". If walking does occur, insure that the perforator is perpendicular.

5. Irrigate while drilling: To cool the cutting edges and wash away the bone chips.

6. While drilling, **hold the perforator steady** and under constant pressure (no tilting or pivoting). Do not apply more pressure than is compatible with the thickness and strength of the patient's bone.

7. **Stop the motor immediately** when:

   - The perforation is perceived as *completed*, or
   - The perforator "clutch" has disengaged.

   Caution: Do not let the motor run while the perforator has disengaged. (This could unnecessarily wear out the clutch mechanism and could compromise its functioning.)

1.4.4.4 **Precautions**:

Because of varying thickness and quality of bone, and because physical pressure is required to achieve cutting, the surgeon should always be especially careful when the perforation is nearly completed. Always be on guard and **prepared to stop drilling, especially in the following situations**:

- In **very thin bone** (less than 3-4 mm). Check the depth of the drill hole frequently, and anticipate completion before the secondary cutter has made contact with the bone (*clutch will disengage* ***only after secondary cutter has reached contact with bone***).

- When **drilling over/near a sinus**: **Check the drill hole frequently, and stop drilling before the inner table is fully penetrated. DO NOT DRILL UNTIL THE INNER CLUTCH "AUTOMATICALLY" DISENGAGES.** Use appropriate hand instruments to break through the innermost layer of remaining bone.

  At times, the perforator may disengage *early* - and will be difficult, or impossible, to engage again:

- If the hole is deep, and offers little resistance, the perforator may disengage before the primary cutter has reached the inner table of the skull.

- Appropriate back-up instrumentation should always be on hand to continue drill holes that cannot be completed by the perforator.

1.4.4.5 General considerations for **care and storage**

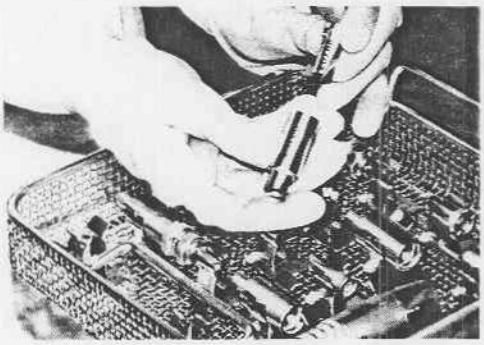
IMPORTANT: When not in use, the perforator should be kept disassembled, with its parts stored in the protective case (for transport, storage, and sterilization).
See also: *ASTM Standard 701-78: Standard Practice for CARE AND HANDLING OF NEUROSURGICAL IMPLANTS AND INSTRUMENTS.*

1.4.4.6 **Assembly Instructions**

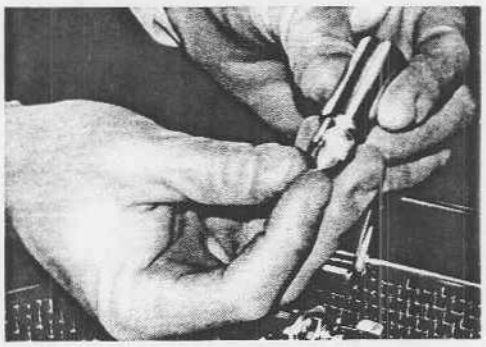
The Cranial Perforator should always be brought to the Operating Room's sterile field disassembled and in the protective case.

WARNING: The serial number on the primary cutter and the secondary cutter must be the *same serial number*. The cutters are produced as "matched sets," and are NOT INTERCHANGEABLE (with the cutters of perforators of the same size).

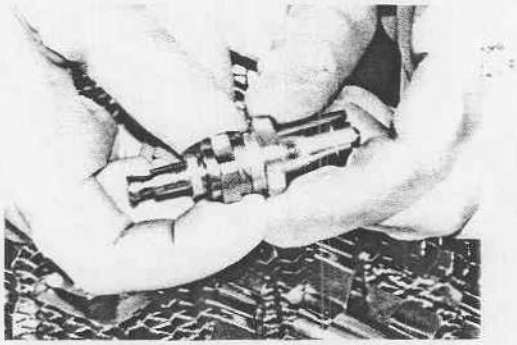
1.4.4.6.1 After confirming that the primary and secondary cutters have the same serial number, the primary cutter is dropped into the sleeve of the secondary cutter.



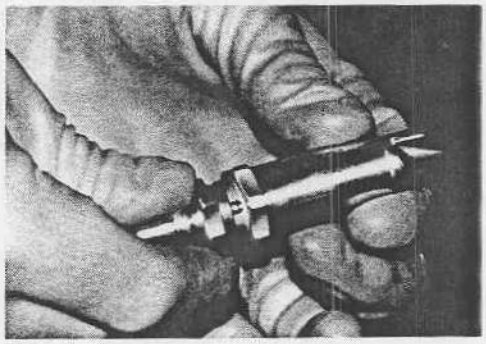
1.4.4.6.2 Be sure that the primary cutter is ***fully seated*** and cannot be rotated. (*It helps to align the flutes of the two cutters* - to enable the primary cutter to "drop into place" in the sleeve of the secondary cutter.)



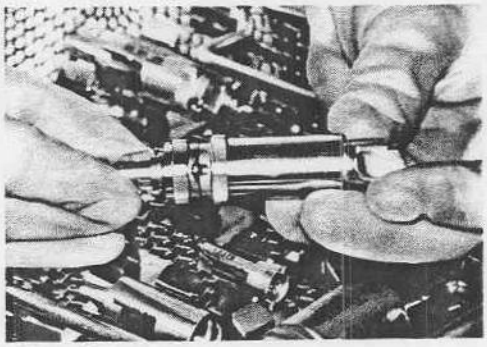
1.4.4.6.3 Rotate the two hexagonal flanges of the main body - so that the release mechanism is in the "unlocked" position.



1.4.4.6.4 Slip the sleeve of the secondary cutter over the main body until both cutters are fully seated.



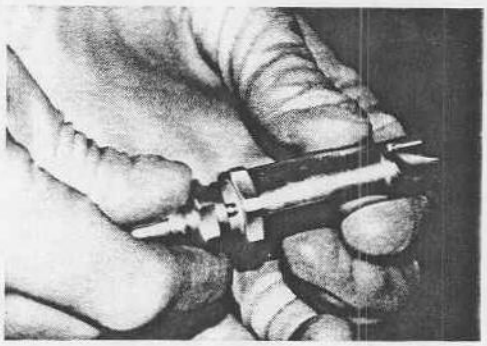
1.4.4.6.5 Rotate the hexagonal flanges until the release mechanism is in the "**locked**" position.



1.4.4.7 **Disassembly Instructions**

At the conclusion of the surgical procedure, the perforator must be disassembled at the instrument table in the Operating Room:

- Rotate the two hexagonal flanges of the main body *in opposite directions* by 1/4 turn.



- The secondary cutter now slides off the main body, and the primary cutter is released.

- The perforator parts should be wiped off, and placed into their assigned partitions of the protective case (in preparation for cleaning and sterilization).

Warning: To prevent damage, do not mix the assembled perforator, or any of its unprotected parts, with other instruments in the basin.

DO NOT IMMERSE THE PERFORATOR IN LIQUID (Liquid might penetrate inside the clutch mechanism of the main body, and cause internal corrosion.).

1.4.4.8 **Cleaning and Inspection** of the Cranial Perforators

Warning: The Cranial Perforator must be disassembled prior to cleaning. A dirty mechanism may interfere with the drilling action and, more importantly, with the self-stopping mechanism.

1. Thoroughly clean the parts with an appropriate non-abrasive antiseptic cleaning solution, and rinse adequately to remove residues of the cleaning solution. Use a soft brush, if necessary, to remove surgical debris.

2. Completely dry all parts (including their inside surfaces) with a soft, lint-free towel.

3. **Lubrication: Slightly lubricate all parts with the special instrument oil (GA059)**, which is sterilizable and physiologically inert.

   Caution: The repeated use of the perforator *without lubrication* may have a negative effect on the automatic disengaging of the clutch mechanism, and may lead to early wear of the instrument. It is strongly recommended to keep the parts of the cranial perforator *slightly lubricated*.

   An accumulation of lubricant, especially in hard to reach areas (inside the main body of the perforator) must also be avoided. Lubrication might harden after repeated sterilizations, and compromise the functioning of the perforator.

4. **Examine all *surfaces*** for corrosion (rust) and mechanical damage. The cranial perforator should be returned to AESCULAP for service if:

   - Any of the functional surfaces exhibit corrosion that resists cleaning, or
   - Mechanical damage has occurred which may alter the safe function.

5. **Examine all *cutting edges*** of the primary and secondary cutters for nicks and dulling. Return the perforator to AESCULAP for resharpening if the cutting edges appear to be worn or damaged.

6. **Examine both sides of the *clutch mechanism***, especially the two "teeth" on the back of the primary cutter. Their faces should be free of wear marks, and their edges should not be rounded off. The "toothing" on the clutch will wear after excessive use, and could eventually cause premature disengagement of the perforator.

7. Check the free play and tension of the clutch spring.

8. Store the perforators disassembled in the protective case provided.

1.4.4.9 **Sterilization** of Cranial Perforators

Sterilization should be performed in accordance with hospital procedures and the autoclave manufacturer's instructions.

High Vac Autoclave:	Standard Cycle (270°)
Gravity Steam Autoclave:	Standard Cycle (250°)
ETO/Gas Autoclave:	Standard Cycle

1.4.4.10 **Pre-Drill TEST PROCEDURE** for the Cranial Perforators

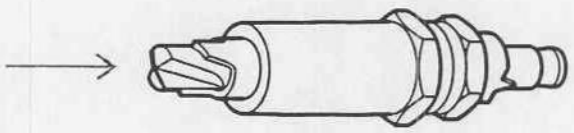
This is mandatory prior to use. Before the perforator is attached to the motor drive:

1. Check the assembly of the perforator: The spring loaded lock between the secondary cutter and the main body must be in the *engaged position* (so that the two hexagonal flanges of the release mechanism are locked against each other).

2. It is recommended that gauze be placed between the perforator tip and the thumb when performing the Pre-Drill TEST PROCEDURE - to avoid puncturing or tearing the surgical gloves.

3. Apply thumb pressure to the tip of the primary cutter:

   - Rotate the main body until the clutch engages, and
   - Check the spring tension by releasing pressure on the primary cutter a few times.



The primary (inner) cutter must:

- Move freely in the axial direction, and
- Disengage readily as thumb pressure is released.

Warning: Do not use the perforator:

- If spring tension is excessive
- If the primary cutter does not move freely, or
- If it remains "engaged" upon release of pressure

4. While the primary cutter is not engaged, rotate the secondary (outer) cutter several turns against the main body:
   - Rotation must be smooth and easy
   - No sticking or grinding may be felt

Warning: Do not use the perforator:

- If rotation is impeded in any way

CAUTION: AESCULAP recommends that the functioning of the perforator, (at least step #3 above) is checked between the drilling of holes during a procedure.

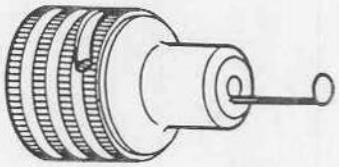
1.4.4.11 **Service** of the Cranial Perforators

AESCULAP offers a complete service for the resharpening and repair of the Craniotome System. **Do not attempt resharpening of the perforator at the hospital** (or at an unauthorized third party).

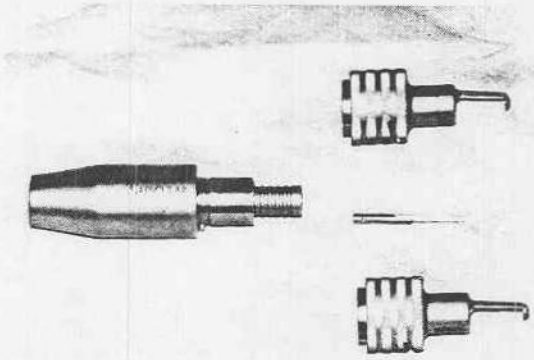
AESCULAP urges hospitals to periodically send perforators for check-up and preventive maintenance service:

- **At least once every six months of use**, or
- **After 100 perforations, whichever occurs first**.

1.4.5 **Craniotome (GB265) Instructions for Use:**



1.4.5.1 Basic Design Rationale



(1) **Fixed Dura Guard (GB298)** - for the surgeon who prefers to *guide* the Dura Guard in the cut made by the craniotome blade

(2) **Rotating Dura Guard (GB266)** - for the surgeon who prefers to hold the craniotome and let the Dura Guard *swivel* ("naturally" following the cut made by the craniotome blade)

(3) **Craniotome blade (MD879)**

(4) **Quick-release chuck**

(5) **Main body of the Craniotome (GB267)**

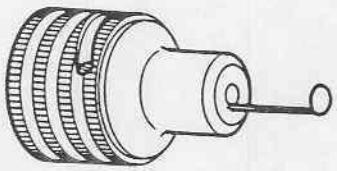
1.4.5.2 Craniotome **function and intended use**

The craniotome has been developed for application in neurosurgery. It is used for cutting out sections of the skull (between burr holes) when performing a craniotomy.

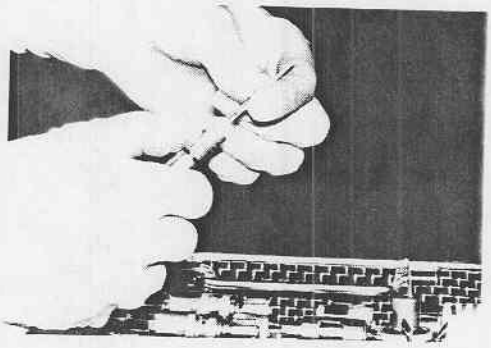
The craniotome can be operated up to 20,000 RPM, with the cutter turning in a clockwise rotation. The cutter "shaves" the bone with each rotation of the blade. The Dura Guard functions as a guide for the cutter while also protecting the dura.

No *special tools* are required for changing either the cutter or the Dura Guard.

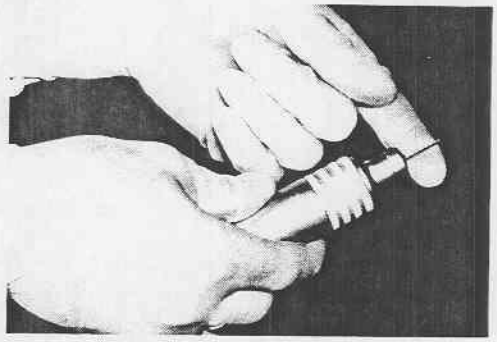
1.4.5.3 **Preparation for Use** of the Craniotome



- Rotate the knurled sheath of the Dura Guard in the clockwise direction, and
- Remove the Dura Guard from the Craniotome.

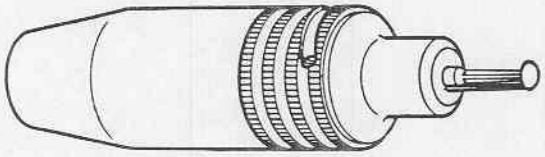


- Remove a **craniotome cutter** from its sterile packaging,
- Pull the collar of the Quick Release Chuck (to the "open" position), and
- Drop the craniotome cutter into place in the Quick Release Chuck,



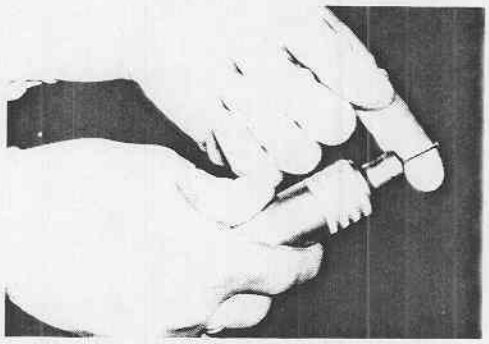
- Rotate the cutter in the chuck until it "seats" in place, and
- Release the collar of the Quick Release Chuck.

NOTE: The collar of the chuck will return to the completely "closed" position ***only*** *when the cutter <u>is completely seated</u> in the base of the chuck.*



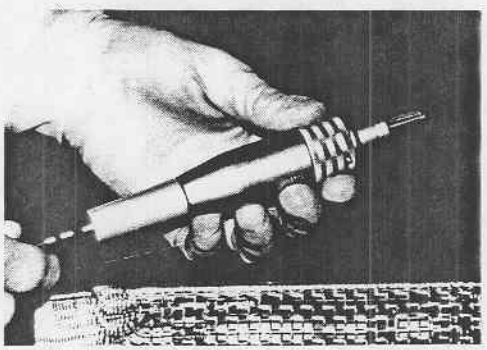
- Put the Dura Guard back on the Craniotome, and
- Rotate the knurled sleeve of the Dura Guard *counter-clockwise* to close/lock it in place.

1.4.5.3.1 **Prior to connection** to the micro cable, **check** the Craniotome



- *Spin* the craniotome cutter by ***lightly*** *passing finger across the cutter.*
  - Cutter should spin "free" - with *minimal* resistance.
  - **Caution: If the cutter does *not* spin "free"**:
    (1) Repeat the steps noted above (to properly "seat" the cutter)
    (2) See Troubleshooting Section of this manual - for additional suggestions.

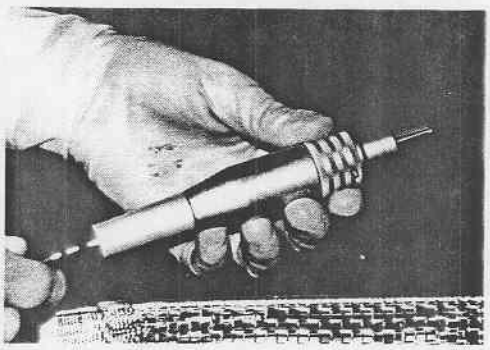
1.4.5.3.2 **To connect the Craniotome** *to the micro cable*:



NOTE: Connect the handpiece to the cable **only** ***when the motor is not running***.

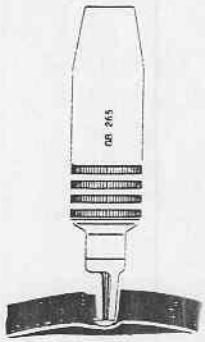
- Grasp the cable at the Small Connector,
- Push the handpiece onto the connector until a "click" is felt/heard.

1.4.5.3.3 **Confirmation** of proper function



- Hold the craniotome, and
- Step on the footpedal of the motor:
  - Start the motor at a slow speed - **the craniotome should run smoothly**
  - Progressively increase the speed - ***minimal* vibration should be felt**

1.4.5.3.4 **During operation** of the craniotome



- After insertion of the Dura Guard through the perforation ("burr hole") in the skull, *the surgeon needs to keep the "flat tip" of the Dura Guard snug against the patient's skull* - **to assure that the guard slides over the dura** as the cutter opens the skull.

- The motor should be run at maximum speed, and the cutter should be irrigated with saline *to keep the cutter running cool and free of surgical debris.*

1.4.5.3.5 To fit a **Wire Pass Burr** into the Craniotome

1.4.5.3.5.1 Remove the Craniotome from the micro cable:

- Hold the micro cable in one hand, and
- Press the "button" on the end of the cable (to release the craniotome) and
- With the other hand, remove the craniotome from the micro cable.

Secure the end of the micro cable in its Special Holder on the Mobile Stand. Remove the Dura Guard (as outlined in Step 1.4.5.3 above).

1.4.5.3.5.2 Remove the craniotome cutter:

- Pull the collar of the Quick Release Chuck (to the "open" position), and
- Remove the craniotome cutter from the chuck,
- Remove the Wire Pass Burr from its sterile packaging, and
- Drop the Wire Pass Burr into place in the Quick Release Chuck.

1.4.5.3.5.3 Assure that the Wire Pass Burr is secured in the chuck:

- Rotate the burr until it "seats" in the base of the chuck, and then
- Release the collar of the chuck.

NOTE: The collar of the chuck will return to the completely "closed" position ***only*** *when the wire pass burr is completely seated in the base of the chuck.*

After the surgeon has utilized the wire pass burr (to close the craniotomy), the burr should be removed from the chuck of the craniotome - and the burr should then be discarded.

1.5 Cleaning the Craniotome System AFTER USE IN SURGERY

1.5.1 Cleaning the **Mobile Stand** (and related components):

1.5.1.1 The motor housing, electrical cables, footpedal, and micro cable can be cleaned by wiping with a dampened cloth.

DO NOT *IMMERSE* IN WATER (or in cleaning solution).

1.5.1.2 The Sterilizable Housing and the Holding Devices (for the micro cable and the mesh basket) can be:

- Immersed in a neutral Ph cleaning solution, wiped clean, and then rinsed.

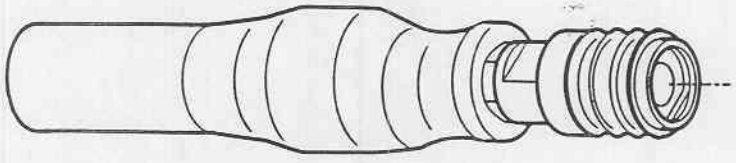
OR they can be:

- Cleaned in a standard washer/sterilizer.

NOTE: Cleaning with *abrasive* cleaners will damage the finish of these items.

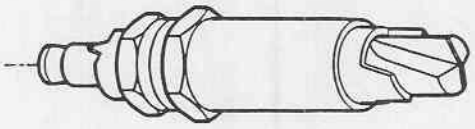
1.5.2 Cleaning the **Handpieces**:

1.5.2.1 Cleaning the **Perforator Handpiece**:



Cleaning is best accomplished with a damp cloth or soft brush. **NEVER IMMERSE THE HANDPIECE** in water or cleaning solutions. Accidentally penetrated water should be drained off *immediately*.

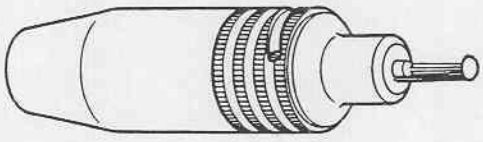
1.5.2.2 Cleaning the **Cranial Perforators**:



Refer to Section 1.4.4.8 (Cleaning and Inspection of Cranial Perforators)

SPECIAL ATTENTION needs to be given to *proper cleaning* and inspection of the Cranial Perforators.

1.5.2.3 Cleaning the **Craniotome**:



1.5.2.3.1 The handpiece should be dis-assembled for proper cleaning.

- Rotate the knurled sheath of the Dura Guard in the clockwise direction, and remove the Dura Guard from the Craniotome.
- If the Craniotome cutter (or Wire Pass Burr) are still in the handpiece, then:
  - Pull the collar of the Quick Release Chuck (to the "open" position)
  - Remove and dispose the cutter (or burr).

1.5.2.3.2 Cleaning is best accomplished with a damp cloth or soft brush.

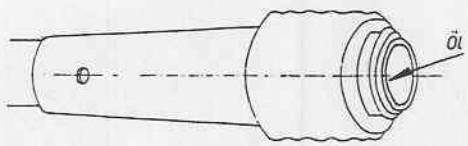
NEVER IMMERSE THE HANDPIECE in water or cleaning solutions. Accidentally penetrated water should be drained off immediately.

1.6 Lubrication and Maintenance

1.6.1 **Motor** and **Mobile Stand** require *no lubrication or routine maintenance at the hospital.*

1.6.2 **Flexible Micro Cable** for the motor:

After each month (of routine use), the connector on the proximal (motor) end requires a few drops of special oil (GA059) at the openings marked "OIL".

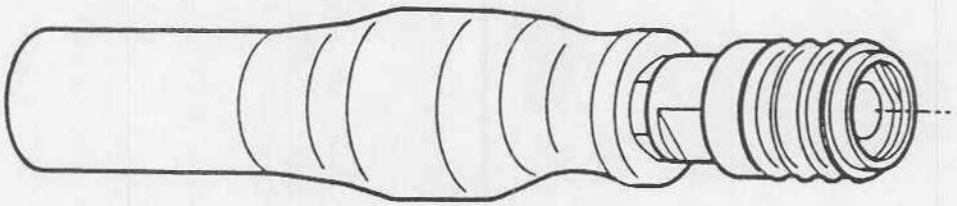


After one year (of routine use), the Micro Cable should be sent to AESCULAP's Repair Facility:

- *To clean and inspect the inner cable, and*
- *To replace the special lubrication inside of the flexible Micro Cable.*

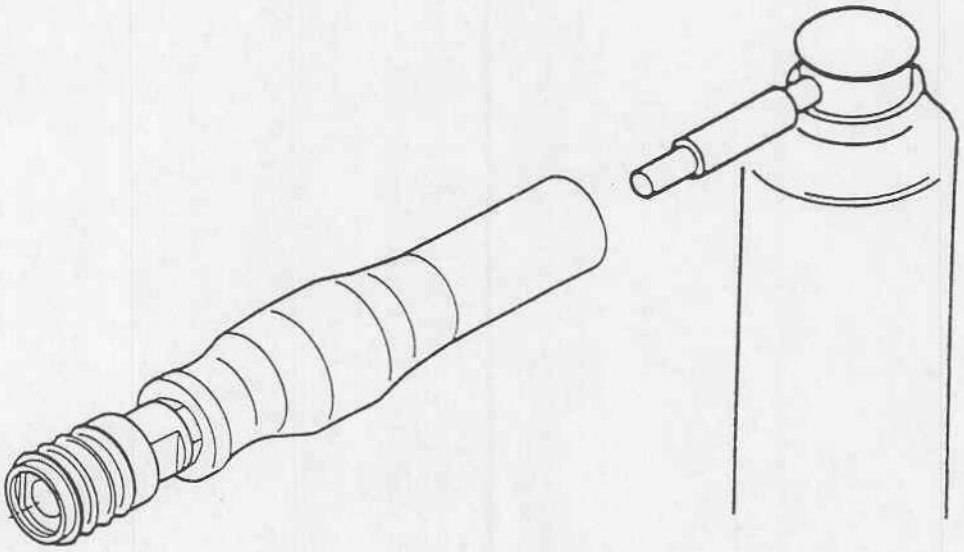
1.6.3 **Perforator Handpiece** (GB169):

After each use (following the cleaning of the handpiece) a drop of the special oil (GA059) should be applied inside the "connector" end:



After each week of use, **send the handpiece to Biomedical Engineering** ***for special sprayed-in lubrication***.

1.6.3.1 The spray nozzle of the GB149 STERILIT OIL SPRAY is inserted into the end of the handpiece:



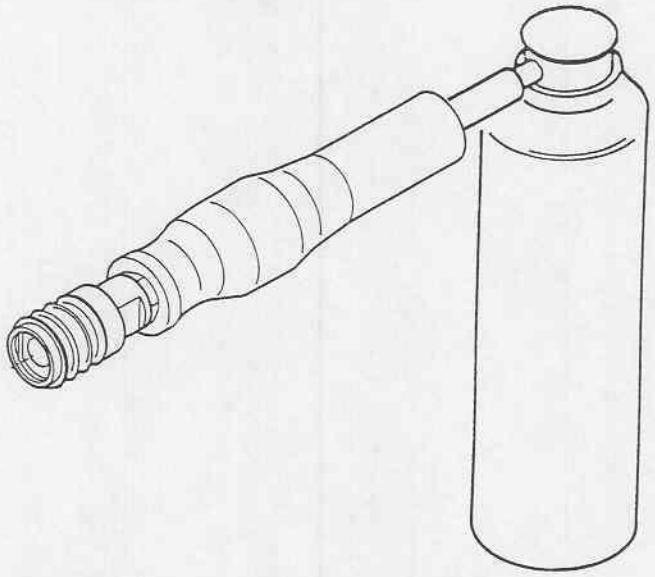
1.6.3.2 With the nozzle ***fully inserted*** **in the connector end of the handpiece**:

- The handpiece tip is positioned over a trash can (or similar receptical)
- The handpiece tip is angled down (at approximately 30 to 45° angle)
- Approximately **one-to-two seconds duration of spray is forced through the handpiece**

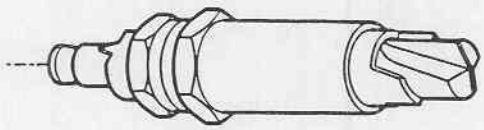
The pressurized lubrication from the GB149 STERILIT SPRAY *forces out moisture (condensate from sterilization) and debris from the inside of the handpiece and* ***assures that the bearings inside the handpiece are provided with adequate lubrication***.

1.6.3.3 **If the spray coming out the end of the handpiece is *not clean/clear*:**

- Connect the handpiece to the micro cable
- Run the handpiece for approximately fifteen (15) seconds
- Disconnect the handpiece from the micro cable
- Insert the nozzle of the STERILIT OIL SPRAY into the handpiece
- Spray for approximately two-to-three seconds *until the spray coming out the distal end of the handpiece is* ***clean/clear***.



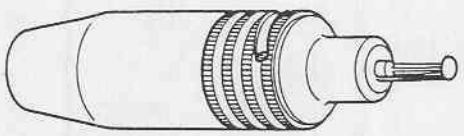
1.6.4 **Cranial Perforators** (GB300, GB302, and GB304):



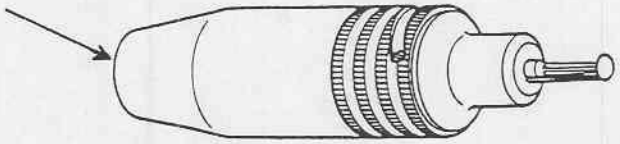
THESE REQUIRE *SPECIAL CARE*.

Refer to Section 1.4.4.8 (Cleaning and Inspection of Cranial Perforators)

1.6.5 **Craniotome** (GB265):



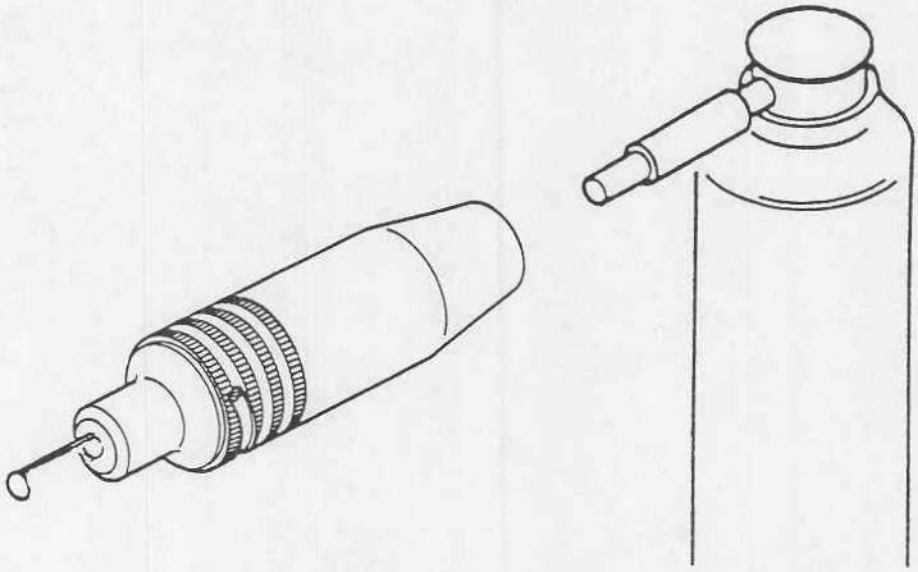
After each use (following the cleaning of the handpiece) a drop of the special oil (GA059) should be applied inside the "connector" end:
After each week of use, **send the handpiece to Biomedical Engineering *for special sprayed-in lubrication*.**



1.6.5.1 Biomedical Engineering uses AESCULAP's **GB149 STERILIT OIL SPRAY to provide special *sprayed-in* lubrication for the handpiece**.

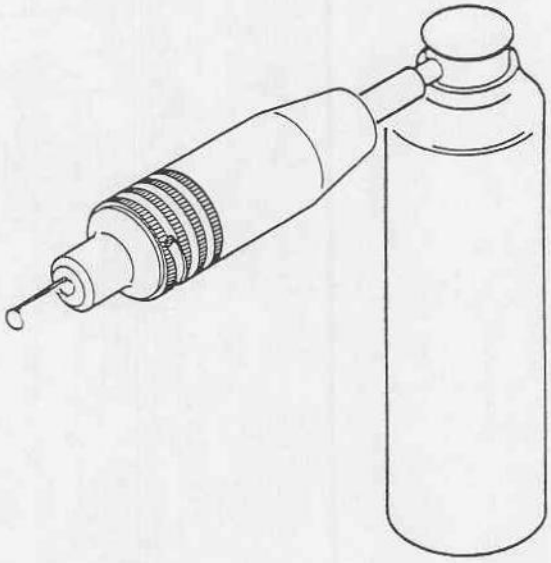
1.6.5.2 **The Cranial Blade is removed from the chuck of the handpiece** *to provide an unrestricted channel for the oil spray.*

1.6.5.3 The spray nozzle of the STERILIT OIL SPRAY is inserted into the end of the handpiece:



1.6.5.4 With the nozzle ***fully inserted*** **in the connector end of the handpiece**:

- The handpiece tip is positioned over a trash can (or similar receptical)
- The handpiece tip is angled down (at approximately 30 to 45° angle)
- Approximately **one-to-two seconds duration of spray is forced through the handpiece**



1.6.3.5 The pressurized lubrication from the GB149 STERILIT SPRAY *forces out moisture (condensate from sterilization) and debris from the inside of the handpiece and* ***assures that the bearings inside the handpiece are provided with adequate lubrication***.

1.6.3.6 **If the spray coming out the end of the handpiece is *not clean/clear*:**

- Connect the handpiece to the micro cable
- Run the handpiece for approximately fifteen (15) seconds
- Disconnect the handpiece from the micro cable
- Insert the nozzle of the STERILIT OIL SPRAY into the handpiece
- Spray for approximately two-to-three seconds *until the spray coming out the distal end of the handpiece is* ***clean/clear***.

1.7 **STERILIZATION** Instructions:

1.7.1 The **Sterilizable Housing** and the **Holding Devices** (for the micro cable and for the mesh basket) can be steam sterilized according to standard protocol:

HiVac autoclave: Standard cycle (270°)
Gravity steam autoclave: Standard cycle (250°)

1.7.2 *DO NOT STERILIZE*: the motor, electrical cables, or the footpedal.

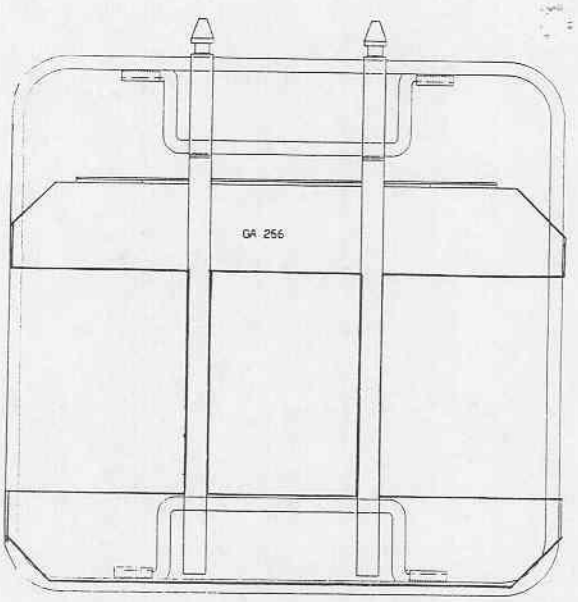
These items should be wiped off with moistened cloth.

1.7.3 STERILCONTAINERs and mesh baskets are provided for sterilization of:

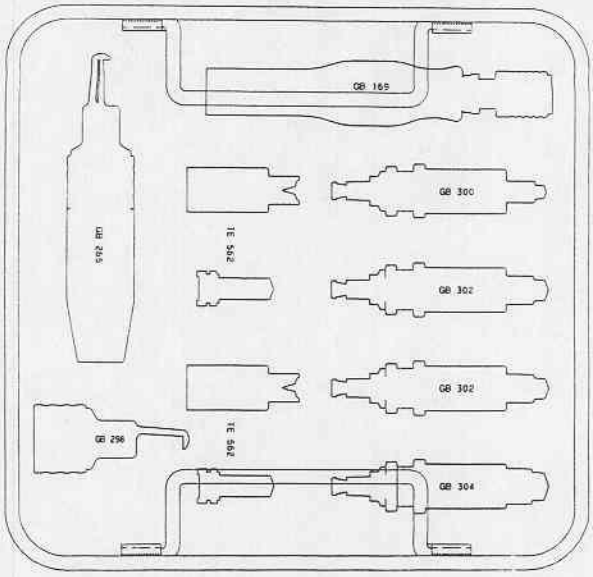
- The Mounting Bracket (which holds the mesh basket on the Mobile Stand)
- The Perforator Handpiece, Cranial Perforators, and the Craniotome.

1.7.3.1 Organization of items in the mesh baskets:

- The Mounting Bracket (GA256) is inverted into the basket



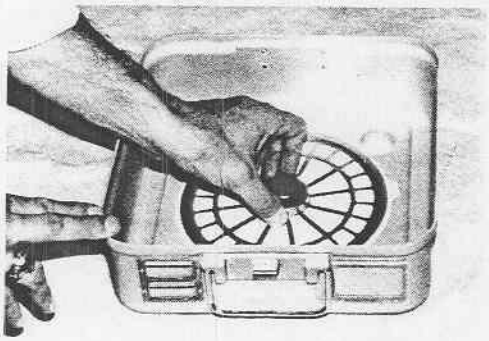
- Special holding clamps secure and organize the handpieces

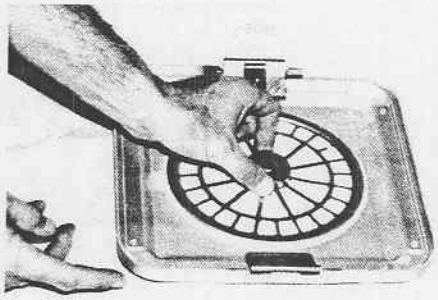


IMPORTANT: **Confirm** that the Primary and Secondary Cutters of the assembled Cranial Perforators have ***the same lot number*** *(as matched pairs)*. The pairs of Spare Cutters should also have *the same lot number*.

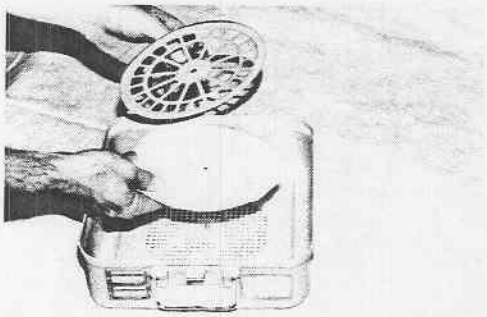
1.7.4 Preparing STERILCONTAINERs for sterilization:

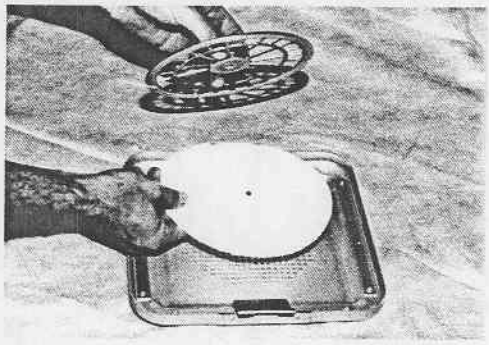
1.7.4.1 **Remove the *used* filter** (from the last sterilization), and **put it a new filter**:



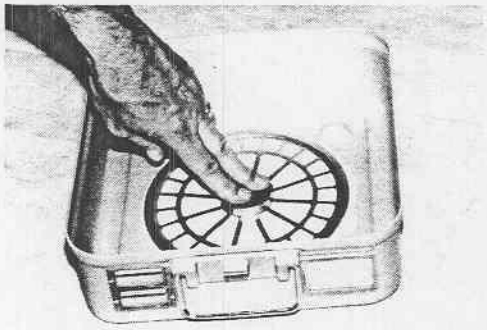


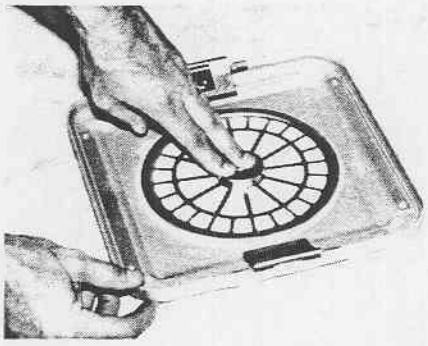
- Squeeze the "buttons" to *release* the filter retainer





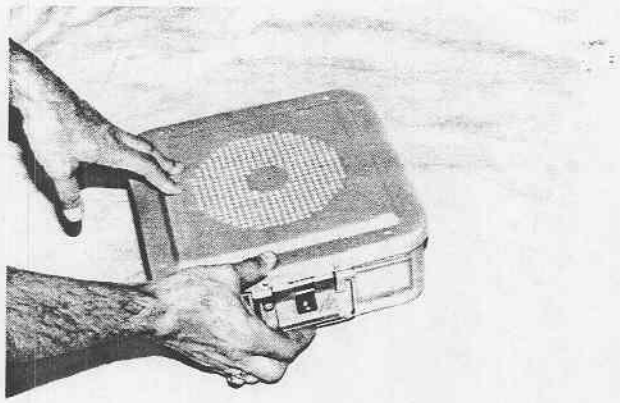
- Lift the filter retainer, and *remove the old filter*





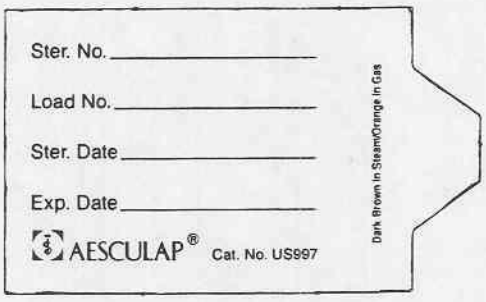
- *Put in a new filter* (US994), place the retainer on its post, and
- *Push down on the center of the retainer* ***until it "snaps" in place.***

1.7.4.2 Place the lid on the container, and close the "*lifting tabs*"



1.7.4.3 **Secure a Plastic Lock** *with steam indicator dot* (US906) through the slot in both of the lifting tabs.

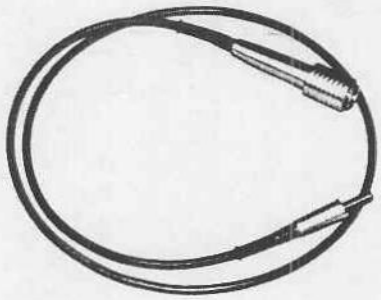
1.7.4.4 **Insert the Indicator Card** (US997) into its holder on the end of the container:



1.7.4.5 The **Mounting Bracket** and **handpieces** can be steam sterilized in their STERILCONTAINERs according to standard protocol:

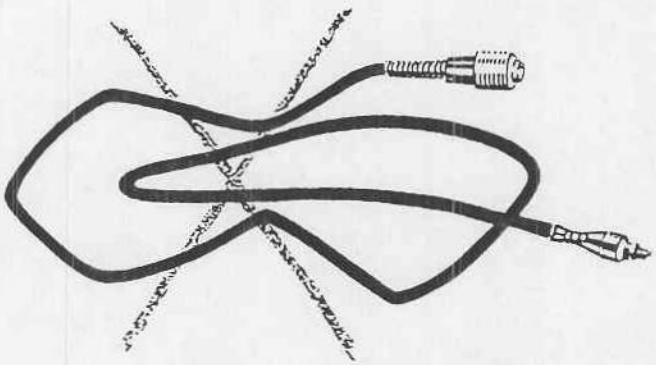
HiVac autoclave: Standard cycle (270°)
Gravity steam autoclave: Standard cycle (250°)

1.7.5 Sterilization of the **flexible Micro Cable** (GA176):



- The Micro Cable should be coiled to a diameter which is *not smaller than 12"* (30 CM).
- Can be steam sterilized according to standard protocol:
  HiVac autoclave: Standard cycle (270°)
  Gravity steam autoclave: Standard cycle (250°)

CAUTION:
Do not *kink* (tightly bend) the Micro Cable - this can damage the inner cable.



1.8 TROUBLESHOOTING GUIDE

PROBLEM:

1.8.1 After the system has been assembled, **the motor will not work** (when the surgeon steps on the footpedal):

- Power Cable:
  - Plugged into outlet?
  - Plugged into back of motor?
- Control Cable:
  - Plugged into footpedal?
  - Plugged into back of motor?
- On Back of Motor:
  - Switch is in the "ON" position?
  - Fuse blown? (use 25 AMP slow-blow type fuse) (two *replacement fuses* are taped to the housing of the Elan-E motor.)

1.8.2 **Perforator (or Craniotome) Handpiece makes *excessive noise* and/or vibrates excessively during operation**:

Send to Biomedical Engineering for *special sprayed-in lubrication* (GB149).
NOTE: After each week of use, these handpieces need this special lubrication.

1.8.3 **Flexible Micro Cable *makes excessive* noise and/or vibrates excessively during operation**:

- The cable has probably gotten "kinked" (from being bent or coiled too tightly).
- **As noted in**:
  - **Section 1.4.2.3 Instructions for Use** - Flexible Micro Cable
  - **Section 1.7.5 Sterilization of the Flexible Micro Cable** (GA176)

The Micro Cable should be coiled to a diameter which is *not smaller than 12" (30 CM)*.

If the inner cable of the Micro Cable has become *kinked* or *frayed:*

- **It must be returned to AESCULAP's Repair Facility** (to have the inner cable replaced).

1.8.4 **Cranial Perforators will not "connect" to the Perforator Handpiece**:

- Slide the Quick Release Adapter sleeve (on the Perforator Handpiece) towards the Cranial Perforator *as far as the sleeve will go*?

- Hudson Connector on the Cranial Perforator "*lined-up*" with the Hudson Connector on the Quick Release Adapter?

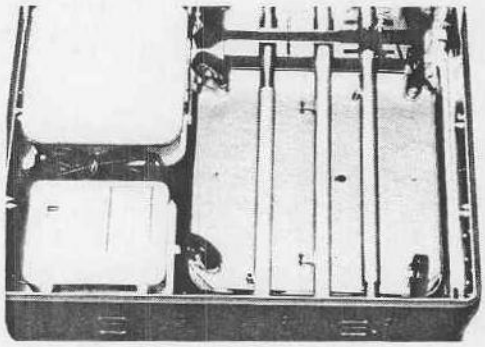
1.8.5 **Cutter Blade on the Craniotome *will not "seat" into the chuck*:**

- Slide the Quick Release Adapter sleeve (on the chuck) away from the Craniotome *as far as the sleeve will go*:
  - While holding the sleeve in the "open" position,
  - *Insert the cutter blade into the chuck,*
  - *Rotate the cutter blade* ***until it "seats" into the chuck***, then
  - Release the sleeve of the Quick Release Adapter.

- **To confirm that the Cutter Blade is *"seated" in the chuck*:**
  - Gently pull on the cutter blade (to confirm it is secured in the chuck)

1.9 STORAGE of the Craniotome System in the SAN Container:

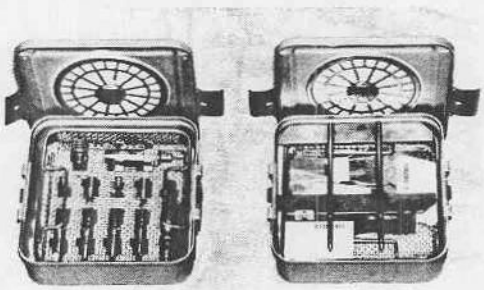
1.9.1 The base of the mobile stand is place upside down in the bottom of the SAN container:



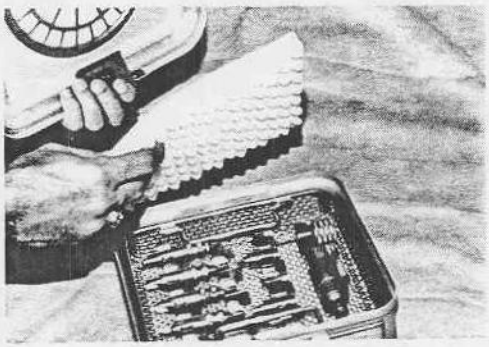
- The tubing sections of the mobile stand are placed into their holding slots

1.9.2 *The mesh baskets and containers are assembled* for storage:

1.9.2.1
- *Foam padding* placed in the bottom of each container,
- Mesh baskets *with handpieces and accessories* are placed in their container.

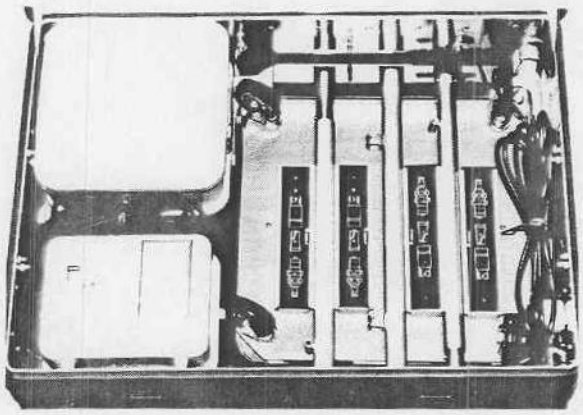


1.9.2.2 The *foam padding* is placed over the mesh baskets, and the lids are latched.

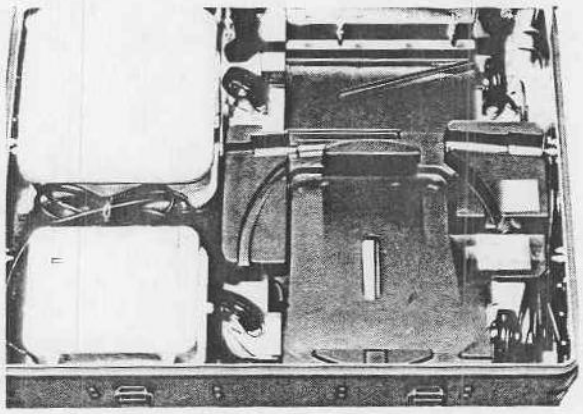


1.9.3 The half-size STERILCONTAINERs are stacked into the top left corner; and the 220Volt *Power Converter* is placed into its space in the bottom left corner of the SAN container.

- *The electrical cable for the Elan-E motor* is coiled next to the base of the mobile stand.

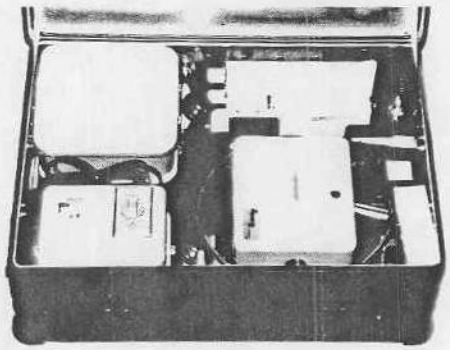


1.9.4 The castors of the mobile stand are rotated toward the outside, and the Intermediate Packing Plate is placed over the base of the stand.



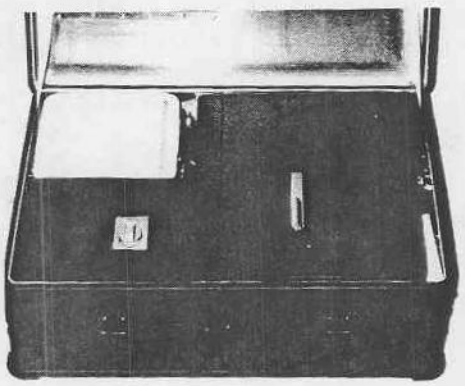
1.9.5

- *The footpedal is placed on its side* in the top right section of the Packing Plate
- *The Elan-E electric motor* (enclosed in the Sterilizable housing) is placed in the center section of the Intermediate Packing Plate
- The large end of the *flexible micro cable* is placed in the packing plate, the cable is coiled into the slot provided. and the small end is secured into place in the special holder (in the front side of the SAN container).



- The *Connecting Cable* is coiled next to the footpedal
- The *Cranio Blades* and *extra Dura Guards* are put in their packaging and fit into the remaining spaces.

1.9.6 The Top Packing Plate is placed over the footpedal, motor, and cables; and packing protection is placed over the Power Converter.



NOTE: The Intermediate and Top Packing Plates MUST BE USED to secure the system components in the SAN container (and avoid damage during transportation).

1.10 WARRANTY Information

The Craniotome System and its components are guaranteed to be free of functional defects in workmanship and materials when used normally (and maintained according to instructions provided in the Operator and Service Manuals) for its intended surgical purpose.

For a period of two years, any components proving to be defective must be returned to AESCULAP, and will be repaired or replaced at no charge.

1.10.1 RETURNED GOODS POLICY (**for handling of WARRANTY complaints**)

Components being returned to AESCULAP *must receive a* ***Returned Goods Authorization (RGA)*** *number*. This number will be issued by AESCULAP's Customer Service Department upon notification of your desire to return the merchandise, and if the return is within this policy. RGA numbers will automatically expire 30 days from the issue if no return is received by AESCULAP within 30 days.

To request an RGA, call AESCULAP Customer Service: (800) 282-9000

Returned goods shipments must be marked on the outside of the package:
"Returned Goods, RGA #_____"

1.10.2 In accordance with Transportation Laws, any items being returned to AESCULAP must be cleaned and sterilized prior to shipment.

1.11 **REPAIRS and SERVICE** of the Craniotome System

1.11.1 AESCULAP recommends that the system be returned for inspection and service:

- After *one year of use*, or
- After *three years of storage*, whichever occurs first.

Components will be checked (for proper function), and internal lubrication will be replaced.

1.11.2 **Cranial Perforators** should be sent for check-up and preventive maintenance:

- **At least once every six months of use**, or
- **After 100 perforations, whichever occurs first**.

1.11.3 REPAIRS and SERVICE should be sent to:
AESCULAP Repair Service
1000 Gateway Boulevard
So. San Francisco, CA 94080
(415) 876-7000

1.12 Re-Order Information

1.12.1 Orders should be sent to:

AESCULAP Customer Service
1000 Gateway Boulevard
So. San Francisco, CA 94080

PHONE: (415) 876-7000 or (800) 282-9000
FAX: (415) 876-0212 OR (415) 876-0432
EDI: (this service to be available from AESCULAP after Mid-1994)

1.12.2 *Components* of the Craniotome System (NSN-6515-01-378-4176):

			(Reference/Page)
GA301X	ELAN-E MOTOR	1 EACH	1.3.2.1 / Page 7
GA304	STERILE HOUSING	1 EACH	1.3.3 / Page 7
GA305	HOLDER FOR MICRO CABLE	1 EACH	1.3.4 / Page 8
GA255	MOBILE STAND	1 EACH	1.3.1 / Page 6
GA256	HOLDER FOR MESH BASKET	1 EACH	1.3.8 / Page 10
GA148U	FOOT SWITCH	1 EACH	1.4.1.1 / Page 12
GA176	FLEXIBLE MICRO CABLE	1 EACH	1.4.2 / Page 13
GB169	PERFORATOR HANDPIECE	1 EACH	1.4.3 / Page 15
GB106	HUDSON ADAPTER	1 EACH	1.4.3 / Page 15
GB300	CRANIAL PERFORATOR, 9MM	1 EACH	1.4.4 / Page 16
GB302	CRANIAL PERFORATOR, 12MM	2 EACH	1.4.4 / Page 16
GB304	CRANIAL PERFORATOR, 15MM	1 EACH	1.4.4 / Page 16
TE563	SPARE CUTTERS, 12MM	2 EACH	1.4.4.6.1 / Page 20
GB265	CRANIOTOME W/ROTATING GUARD	1 EACH	1.4.5 / Page 26
GB266	ROTATING DURA GUARD	1 EACH	1.4.5 / Page 26
GB298	FIXED DURA GUARD	2 EACH	1.4.5 / Page 26
JN010P	STERILCONTAINER, HALF SIZE	2 EACH	1.3.7 / Page 9
JF489	MESH BASKET, HALF SIZE	2 EACH	1.3.7.3 / Page 10
GA059	**SPECIAL OIL**	**1 EACH**	**1.6.2 / Page 32**
XB391X	SAN CONTAINER (B20/2Y)	1 EACH	1.9.1 / Page 43
XB392X	220VOLT CONVERTOR	1 EACH	1.9.3 / Page 44
US450	CASE FOR PERFORATORS	4 EACH	1.4.4.7 / Page 22
MD879	STERILE CRANIO BLADES, 5/BOX	2 BOXES	1.4.5.1 / Page 26
US419	STERILE WIRE PASS BURRS, 5/BOX	2 BOXES	1.4.5.3.5/Page 29

1.12.3 **SPARE PARTS** and Supplemental Items

		(Reference/Page)
GD502/800	POWER CABLE (FOR GA301 MOTOR)	1.3.5 / Page 8
GD407	CONTROL CABLE (FOR GA148U FOOTPEDAL)	1.3.5 / Page 8
XB378X	BOTTOM PACKING PLATE (FOR SAN CONTAINER)	1.9.1 / Page 43
XB379X	INTERMEDIATE PACKING PLATE (FOR SAN CONTAINER)	1.9.4 / Page 44
XB387X	TOP PACKING PLATE (FOR SAN CONTAINER)	1.9.6 / Page 45
JK029P	LID (FOR HALF SIZE CONTAINER)	1.7.4 / Page 38
JN040	BOTTOM (FOR HALF SIZE CONTAINER)	1.7.4 / Page 38
TE673	RETENTION PLATE (FOR LID OR BOTTOM OF CONTAINER)	1.7.4 / Page 38
GB149	**STERILIT OIL SPRAY, 6 CANS/BOX**	**1.6.5.3 / Page 35**

SUPPORT KIT: Processing Pack for the HALF SIZE CONTAINERS

US901	PROCESSING PACK	1 EACH	
	Consists of:		
	2 BX. US994/FILTERS;		1.7.4.1 / Page 38
	2 BX. US906/TAMPERPROOF LOCKS; and		1.7.4.3 / Page 39
	4 BX. US997/INDICATOR CARDS.		1.7.4.4 / Page 39

1.13 ENVIRONMENTAL LIMITATIONS DURING STORAGE

When stored in the SAN container, the temperature should be maintained in the following range:

$-22^{\circ}F$ to $+ 103^{\circ}F$ ($-30^{\circ}C$ to $+39^{\circ}C$)

Humidity up to 95% can be tolerated for prolonged periods.